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Abstract

Operative vaginal birth (OVB) remains, in skilled hands, the most efficient way of expediting birth in the second stage of labour and is associated with fewer poor maternal and neonatal outcomes. However, multiple factors including training requirements, patient perception and medico-legal pressures have resulted in a steady reduction in the proportion of births being expedited with OVB. The BD Odon Device is a new device for OVB which is envisaged to mitigate these pressures and reduce the number of Caesarean sections performed in the second stage of labour.

Before introduction into clinical practice, any new device must be thoroughly and systematically evaluated to determine how likely it is to be used effectively, repeatably and safely. In this thesis I present an approach to this problem specific to new devices for operative vaginal births.

Simulated operative vaginal births using the BD Odon Device demonstrated that the device sits on the fetal head in a repeatable, predictable and potentially safe way. The device generates more perineal distention than commonly used ventouse devices, and generates more pressure on the fetal head than ventouse, but less than forceps. It can be used intuitively by the majority of accoucheurs following brief structured training. This combination of features suggests that, with appropriate training, it may be used in a variety of healthcare settings (including areas where OVB is infrequently used) and generate beneficial outcomes for women and babies.

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And finally, to my family, with all my love.

Declaration of Originality

I declare that the work in this dissertation was carried out in accordance with the requirements of the University's *Regulations and Code of Practice for Research Degree Programmes* and that it has not been submitted for any other academic award. Except where indicated by specific reference in the text, the work is the candidate's own work. Work done in collaboration with, or with the assistance of, others, is indicated as such. Any views expressed in the dissertation are those of the author.
Each chapter/study presented in this thesis was written by myself, Stephen O'Brien. The assistance of my co-authors is acknowledged:

* Chapter 2 (Position) – S O'Brien performed all simulations and collected data. E Lengeurrand performed the statistical data analysis. C Burden, C Winter, M Boulvain, T Draycott and J Crofts supervised the study.
* Chapter 3 (Perineal distention) - S O'Brien performed all simulations and collected data. E Lengeurrand performed the statistical data analysis. C Burden, C Winter, M Boulvain, T Draycott and J Crofts supervised the study.
* Chapter 4 (Traction) – S O'Brien performed all simulations and collected data. E Lengeurrand performed the statistical data analysis. C Winter, M Boulvain, T Draycott and J Crofts supervised the study.
* Chapter 5 (Pressure) - S O'Brien performed all simulations and collected data. E Lengeurrand performed the statistical data analysis. C Winter, M Boulvain, T Draycott and J Crofts supervised the study.
* Chapter 6 (Human factors) – S O'Brien, J Crofts and A Mouser conceived the idea and designed the study. A Ignacio drafted all diagrams for the instructions for use. S O'Brien and A Mouser collected the data. T Sumitro, D Alisanto and W Leng Lim assisted in data collection. S O'Brien analysed the data and wrote the draft. J Crofts assisted in data interpretation. C Winter, T Draycott and J Crofts supervised the study.

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O'Brien, S, Winter, C, Burden, C, Boulvain, M, Draycott, T & Crofts, J, 2017, 'Pressure and traction of a model fetal head and neck associated with the use of forceps, Kiwi ventouse and the BD Odon Device in operative vaginal birth: a simulation study'. *BJOG* 2017 Sep 21;124(S4):19-25

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Abbreviations

Bipareital Diameter	BPD
Body Mass Index	BMI
Caesarean section	CS
Electronic Fetal Monitoring	EFM
Food and Drug Administration	FDA
High Income Country	HIC
Human Factors Engineering	HFE
Instructions for Use	IFU
Left Angle of Mandible	LAoM
Left mid-vestibular edge	LMVE
Low or Middle Income Country	LMIC
Medicines and Healthcare products Regulatory Agency	MHRA
National Health Service	NHS
National Institute for Health Research	NIHR
Neonatal Intensive Care Unit	NICU
Obstetric Anal Sphincter Injury	OASI
Occipito-Anterior	OA
Occipito-Posterior	OP
Occipito-Transverse	OT
Operative vaginal birth	OVB
Pelvic Organ Prolapse	POP
Posterior Fourchette	PF
Postpartum Haemorhhage	PPH
Randomised Controlled Trial	RCT
Right Angle of Mandible	RAoM
Right mid-vestibular edge	RMVE
Royal College of Obstetricians and Gynaecologists	RCOG
Subgaleal Haemorrhage	SGH
World Health Organisation	WHO

Chapter 1 General Introduction

1.1 Definition of operative vaginal birth

Operative vaginal birth (OVB) is a procedure performed in the final part of the second stage of labour in which the operator uses either forceps or a vacuum device to promote the extraction of the fetus from the birth canal. The goal of operative vaginal birth is to facilitate vaginal birth, hence expediting the birth whilst minimising maternal or neonatal morbidity (1).

1.2 Managing the risk of birth

Birth is a predictably risky moment for both a woman and her baby. Prior to the advent of modern medical practices, death in childbirth was common – in 1700 approximately 100 in 100,000 births in the UK resulted in a maternal death (2). Maternal mortality has fallen precipitously since then, and currently stands at 3.9 per 100,000 births worldwide (3) – while this is a welcome improvement, death in pregnancy, childbirth and the puerperium remains the second most common cause of death in women worldwide (4).

Within this, complications of the second stage of labour (fetal compromise, obstructed labour, maternal exhaustion or maternal medical conditions exacerbated by the act of pushing) remain a major cause of maternal and neonatal mortality and morbidity across the world. Such complications are responsible for 4 to 13% of maternal deaths in Africa, Asia, Latin America and the Caribbean (5), and in 2013 obstructed labour alone accounted for 0.4 deaths per 100,000 women worldwide (3).

These complications can be mitigated either by (i) delivering the fetus to change its mechanism of respiration to direct absorption of oxygen through it's lungs and thereby treating the hypoxia or (ii) relieving the pressure generated on maternal and neonatal tissues by a fetus that remains within the birth canal in the setting of an obstructed labour or an exhausted mother. This can be achieved by the accoucheur performing either an operative vaginal birth or a Caesarean section - when performed in an appropriate setting by skilled accoucheurs, operative vaginal birth can reduce adverse outcomes for women and their babies relative to Caesarean section (6). While recent improvements have been made in maternal outcomes following Caesarean section, for example through the use of new generations of uterotonics (7), OVB remains a useful and viable strategy for the management of complications in the second stage of labour (8).

Historically accoucheurs have used either obstetric forceps or ventouse to expedite birth. The first reported use of obstetric forceps was in the 16th Century (9), and ventouse entered widespread practice in the 1950s as an alternative (10). Both obstetric forceps and ventouse are independently associated with increased maternal and neonatal morbidity, including; maternal perineal trauma, neonatal facial injury (forceps), cephalohaematoma, subgaelal haemorrhage, and retinal detachment (ventouse) (11). However, despite this and in an era with rising Caesarean birth rates, there have been few innovations to assist vaginal birth. New developments are needed to arrest the decline in OVB rates, and increase the use of appropriate OVB, in order to promote better maternal and neonatal outcomes. Therefore it is reasonable to develop new instruments for OVB, in addition to increased promotion of existing ones (8,12). This logic has laid behind the project of this doctoral thesis – to develop a simulation-based methodology for evaluating new devices for OVB prior to clinical use. This general introduction will review the current options for managing complications in the second stage of labour, worldwide trends in OVB, factors that may play a role in the clinical outcomes of OVB and how positive outcomes from OVB could be promoted. It will also describe how a new device for OVB may, through its mechanism of action and design, mitigate the downward pressure on OVB and enable better maternal and neonatal outcomes following OVB.

1.3 Current instruments for OVB

Non-rotational forceps (Simpson's, Rhode's/Neville-Barne's and Wrigley's), solid mushroom cup ventouse (Malström, Bird's and Kiwi), bell cup ventouse (silastic) and rotational forceps (Kiellands) are the most common obstetric instruments currently in use. The devices are associated with different adverse outcome profiles and relative benefits for different clinical presentations (i.e. non-rotational vs rotational births), as well as specific differences between devices. All of these have an impact on the utilisation rates of not only the individual instruments, but also on OVB as a whole relative to Caesarean section.

1.3.1 Non-rotational births

A non-rotational birth is an OVB where the fetal head is not rotated (either actively (rotational forceps/manual rotation) or passively (rotational ventouse)) by the accoucheur as part of the OVB. Non-rotational births can be performed using non-rotational forceps, solid mushroom cup or bell ventouse – of these, forceps tend to be more successful and associated with less harm to the baby, but more to the mother. This was demonstrated in the most recent Cochrane review of 10 randomised trials involving 2923 women. This found that the use of forceps was associated with a lower risk of failure with the primary instrument (RR 0.65) compared to ventouse (11). While this is an important finding given the known significantly higher rates of maternal and neonatal adverse outcomes associated with the use of sequential instruments, other significant differences remain. Relative to forceps, ventouse is:

- more likely to be associated with cephalhaematoma (OR 2.4; 95% CI 1.7 to 3.4)
- more likely to be associated with retinal haemorrhage (OR 2.0; 95% CI 1.3 to 3.0)
- more likely to be associated with maternal worries about baby (OR 2.2; 95% CI 1.2 to 3.9)
- less likely to be associated with significant maternal perineal and vaginal trauma (OR 0.4; 95% CI 0.3 to 0.5)
- no more likely to be associated with delivery by caesarean section (OR 0.6; 95% CI 0.3 to 1.0)
- no more likely to be associated with low 5-minute Apgar scores (OR 1.7; 95% CI 1.0 to 2.8)
- no more likely to be associated with the need for phototherapy (OR 1.1; 95% CI 0.7 to 1.8). (12)

and possibly less likely to be associated with higher long-term morbidity as a result of pelvic organ prolapse (13), although this association has not been shown in recent population-level studies (14,15).

Despite the apparent superiority in most maternal and neonatal outcomes for forceps in non-rotational births, the use of forceps is generally lower worldwide than ventouse (16).

1.3.2 Rotational births

A rotational birth is an OVB where the fetal head is rotated (either actively (rotational forceps/manual rotation) or passively (rotational ventouse)) by the accoucheur as part of the OVB. Rotational births can be performed using mushroom cup ventouse (Bird's or Kiwi cup), manual rotation followed by direct forceps birth, or rotational forceps.
Rotational births have long been perceived by accoucheurs as being proportionally more risky than non-rotational OVBs (17) – reflecting this, the most recent RCOG guideline specifies that they should be conducted in theatre in the presence of an experienced operator (12). Although some small studies in previous decades have shown poorer neonatal outcomes following attempted rotational forceps births relative to Caesarean section (18), larger, more recent studies have shown that attempted rotational birth (using any of the three approaches) is not inherently more risky than the alternative (Caesarean section) (20-22), and generates comparable outcomes to non-rotational OVB (23,24). This has generated a renewed interest in the technique for the management of malposition of the fetal head at full cervical dilatation, as a viable alternative to Caesarean section (25-27). Despite this renewed interest, debate remains about the most effective instrument for rotation and delivery of the fetal head - while the relative efficacy of all three of these approaches has only been compared in one retrospective cohort study (Bahl et al., 2013) (19), other studies have examined outcomes of various combinations of the two of the three approaches.

1.3.2.1 Rotational forceps versus rotational ventouse

Rotational forceps appear to be superior to rotational ventouse. The only meta-analysis of available studies, conducted in 2015 and analysing 8 studies (7 retrospective cohort studies and one prospective cohort study, total 2399 patients) reported a statistically significant reduced risk of failure to deliver with the intended instrument using rotational forceps over rotational ventouse (RR 0.32 (95% CI 0.14 to 0.76; $p = 0.009$), with no significant differences found in any adverse maternal or neonatal outcomes (20)

1.3.2.2 Rotational forceps versus manual rotation followed by direct forceps

Two UK-based retrospective cohort studies have directly compared rotational forceps and manual rotation followed by direct forceps, and these have found varying levels of differences in outcomes; Bahl et al. found no differences in any maternal or neonatal outcomes (19), while a study published by O'Brien et al. found a significantly higher chance of vaginal birth using rotational forceps than with manual rotation followed by direct forceps (RR 1.17, 95 % CIs 1.04 to 1.31, $p = 0.017$). Additionally, births by rotational forceps were associated with a significantly higher rate of shoulder dystocia (RR 2.35, 95% CIs 1.23 to 4.47, $p = 0.012$), but not of any other maternal or neonatal injuries (21). Both of these studies are however limited by their design (retrospective cohort studies) and setting – both studies were restricted to one unit only, in the same city (Bristol, UK). Moreover, the actual number of accoucheurs performing the rotational forceps births reported in each study was low (three accoucheurs in O'Brien et al.). This raises the possibility of the specific practitioners being more than usually experienced and may limit the applicability of the study's findings.

1.3.2.3 Manual rotation followed by direct forceps versus rotational ventouse

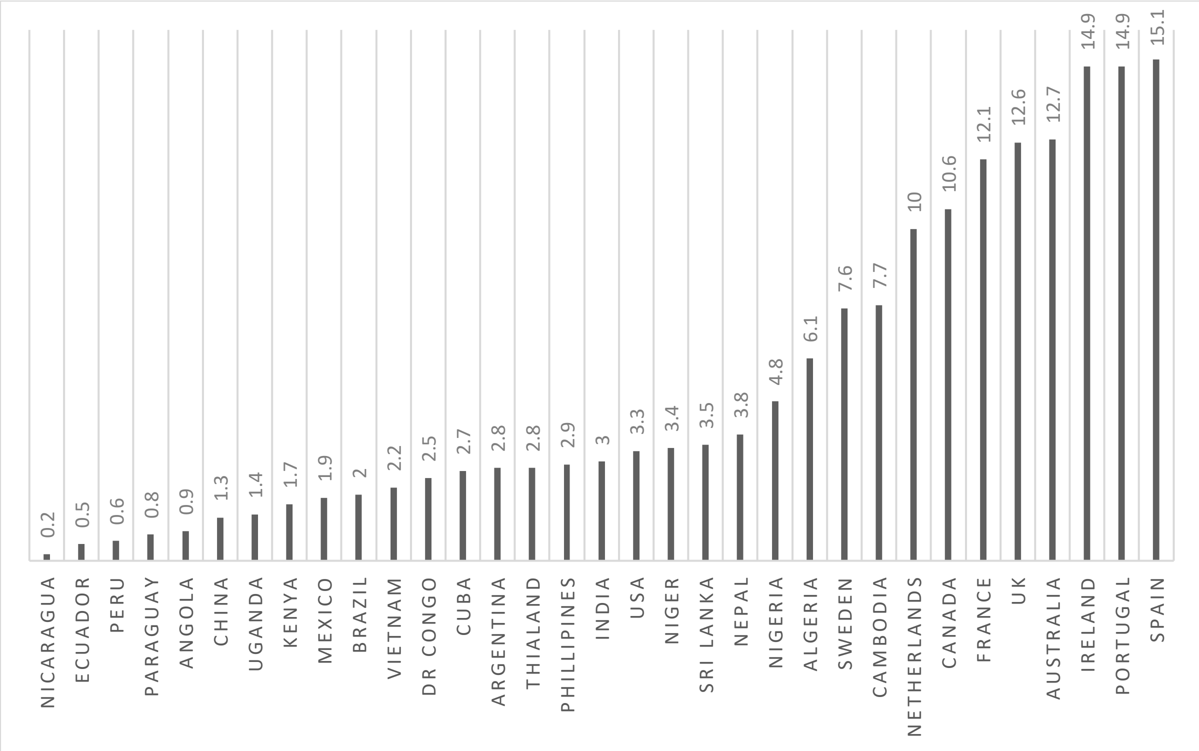
Success rates of manual rotation followed by direct forceps versus rotational ventouse were examined by Bahl et al. in their 2013 retrospective cohort study of 236 women. They found no significant differences in any outcomes between the two approaches (19).
Despite renewed interest, the performance of rotational OVB remains relatively specialised and comparatively rare – in the USA in 1996 a majority of obstetricians had abandoned rotational OVB in favour of Caesarean section (22).

1.4 Trends in OVB

1.4.1 Current state of OVB

OVB is currently performed frequently (10 to 15% of births) in the UK, Ireland, France, Spain, Portugal, Canada and Australia, infrequently in Algeria, Sweden and Cambodia (5 to 10% of births), and rarely (less than 5% of births) in the United States of America and most low and middle-income countries (LMICs). Rates of OVB in selected countries are shown in Figure 1-1 (23-25) (26).

Figure 1-1. Percentage of births as OVBs in selected countries, 2008 to 2015



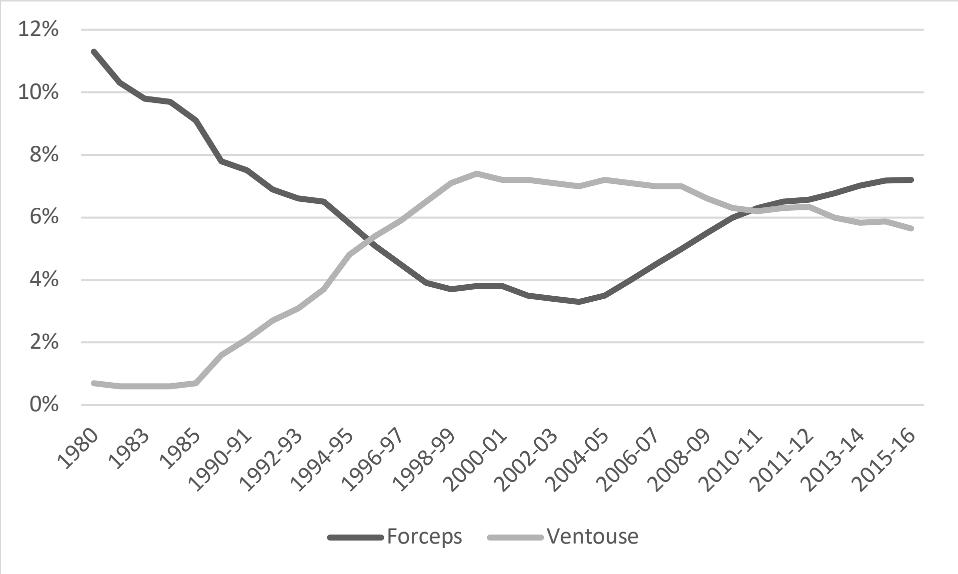
* Data adapted from (23–25) (26)

In addition to widespread low levels of utilisation, earlier surveys found significant areas where OVB was not used at all – in 2006 this was the case in 17 of 23 Latin American & Caribbean countries, as well as 30% of countries in sub-Saharan Africa and 40% of countries in Asia (27). This confirms that there is a wide disparity in the utilisation of OVB between high-income countries (HICs) and low and middle-income countries (LMICs).

1.4.1.1 OVB within high-income countries

Rates of OVB appear to have remained broadly stable within most high-income countries (HICs), although the utilisation of forceps versus ventouse has changed over time, with forceps declining and the rate of ventouse increasing. For example, in the UK in 1980, the overall OVB rate was 12%, with 11.3% of all births being performed with forceps versus 0.7% performed by ventouse (28). By 2017 the overall rate of OVB was 12.8%, with 7.2% of all births performed by forceps and 5.6% performed by ventouse (29) – this trend is shown in Figure 1-2.

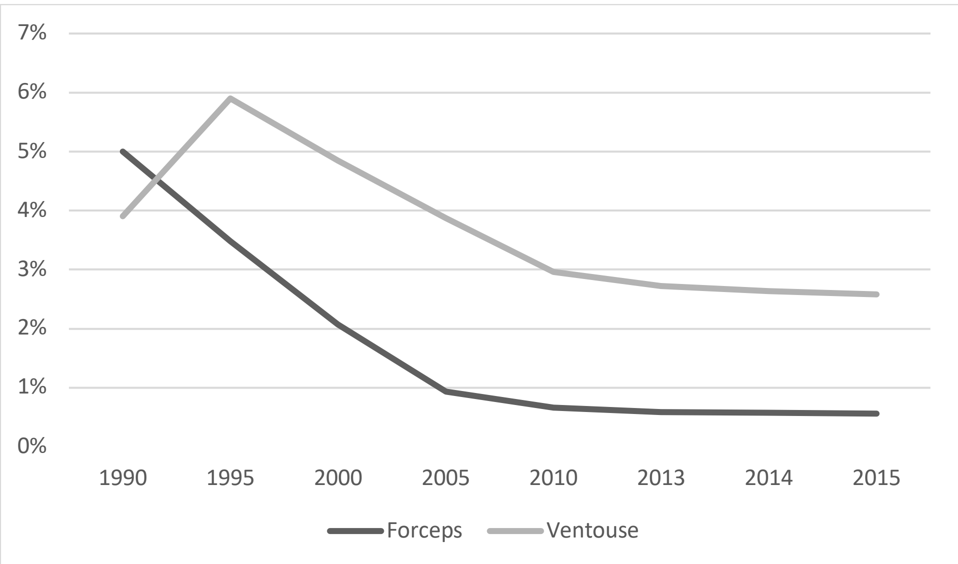
Figure 1-2. Percentage of births performed with forceps and ventouse in the UK, 1980 to 2016



* Data adapted from NHS Maternity Statistics, annually from 1980 to 2016

There has been a similar shift in Australia, where from 1991 to 2013 the overall OVB rate increased, from 12.5% to 18%, with forceps deliveries reducing from 10% of births to 7% while ventouse increased from 2.5% to 11% (30) (31). The exception to this pattern of broadly stable, relatively high OVB rates in HICs is the USA. In the USA rates of OVB (both forceps and ventouse) have consistently declined in the past 30 years, from a level broadly comparable with European countries (9% of all births in 1990) to a current low of 3.12% in 2015, of which forceps were 0.56% (32) – this trend is shown in Figure 1-3.

Figure 1-3. Percentage of births performed with forceps and ventouse in the USA, 1990 to 2015



* Data adapted from (32)

1.4.1.2 Drivers of low OVB rates in some HICs

Recent declines in the utilisation rate of both forceps and ventouse have been observed in the USA, and until recently, lower rates of forceps births were observed in the UK (see Figure 1-2). Multiple factors have been proposed as contributing to these declines – these include the ability of junior obstetricians to learn these complex procedures (33), the regulatory environment (34), and patient perception of these interventions (35).

1.4.1.2.1 Development of skills in junior obstetricians

OVB is an complex skill that requires an understanding of the anatomy, constant re-evaluation of the situation, fine motor skills that respond to haptic feedback, and continuous simultaneous communication with both professional colleagues and the patient (36). Experienced accoucheurs can find it difficult to clearly identify, describe and transfer the skills required to perform an OVB, as much of the process has been internalised by the time they become an identified 'expert' (41,42). Despite recent attempts to clearly define the thinking process, decision points and manual skills required to perform OVB (41,42), the majority of useful learning by junior accoucheurs is conducted via 'learning-on-the-job', performing either parts or whole OVBs under direct, often hands-on supervision from a senior accoucheur (37) – this is necessarily dependent on exposure to suitable clinical situations on a Labour Ward.

The working hours of junior doctors within the UK have dramatically reduced compared to a generation ago – in 1990, over 70% of first-year graduates in hospitals were contracted to work more than 70 hours a week, and 30% were contracted to work more than 100 hours a week (38). This has reduced to an average of 48 hours per week as of 2014 (39). This reduction in junior doctor presence has been mirrored by an increase in senior presence on Labour Wards – since 2013, the RCOG has recommended that large units (>4500 births per year) work toward achieving 24-hour consultant presence on Labour Ward (40). While there is good evidence that this shift in workload patterns away from junior medical staff does not affect end clinical outcomes for patients (41), the relative reduction in clinical exposure may explain the lack of confidence among obstetrics and gynaecology (O&G) trainees in undertaking more complex OVBs. This was highlighted in the 2013 annual General Medical Council survey of trainees regarding the management of malposition of the fetal head at full cervical dilatation (33). This is further evidenced by the shift in later acquisition of complex

OVB skills – while in 1979 relatively junior obstetricians routinely performed rotational forceps deliveries (18), the vast majority of these OVBs are now undertaken by trainees with at least 6 years of experience (20,24). This effect can still be seen in the levels of familiarity and use of rotational forceps among obstetricians of different generations, demonstrated in a survey of all practising and retired obstetricians in Northern Ireland in 2009. In this survey, 82% of retired consultants felt comfortable with the use of rotational forceps, while only 22% of current consultants did so. Moreover, while 54% of current trainees had performed at least one rotational forceps birth, none had done so independently (42).

Obstetricians in training in the USA have been shown to need to perform at least 12 independent, unsupervised forceps births prior to the end of their training in order to be likely to use forceps themselves in later, independent practice (43). With the shifting of the acquisition of some complex OVB skills toward the end of the training program, the time available for the embedding of these newly acquired skills reduces. This may therefore help to explain the reduction in the number of fully qualified obstetricians who, in the USA, perform rotational operative birth at all (22), or in the UK, use rotational forceps (42).
It may therefore be reasonable to assume that while this shift away from obstetricians being both present and learning relatively complex skills early in their career may reduce the risks exposed to women and their babies during the training itself but may come at the expense of the acquisition of skills at a stage of training which will allow them to become solidified and utilised in later practice.

1.4.1.2.2 Public perception

OVB in general, and forceps in particular, do not possess a positive public image. While no studies have directly evaluated women's perceptions of OVB, a negative media environment surrounding OVB, particularly forceps, does exist (16). This is reflected in coverage such as negative newspaper headlines following adverse outcomes after the use of OVB (35), recent political campaigns to ban the use of forceps within individual jurisdictions in the USA (16) and the positive media response to these campaigns (44). While it is difficult to quantify the effect of these drivers on actual rates of OVB, it would be reasonable to assume that this negative perception would result in some women expressing a preference for a Caesarean section over an indicated OVB.

1.4.1.2.3 Concerns over long-term maternal outcomes

In recent decades, evidence has begun to emerge regarding long-term urogynaecological outcomes and mode of birth. Any form of vaginal birth is associated with an increased risk of reporting symptoms of pelvic organ prolapse (POP) - large-scale epidemiological studies have found this to be between 2 to 5 times that following Caesarean birth alone (45,46). Within this increased risk, multiple retrospective cohort studies have found increased risks of symptoms in those women who underwent OVB, with the increase in risk varying between 1 to 2 times that following normal birth (14,15,47,48).

Furthermore, some studies have found increases in symptoms among women who have had forceps births relative to those who have had ventouse births (13,15) – however, this finding has not been replicated in all studies (14). While there is no direct evidence that these emerging concerns directly affect individual clinical decisions, they are likely to be borne in mind by practising obstetricians and will contribute to a reasonable perception that OVB is not without long-term maternal risks which should be communicated to the woman at the time.

1.4.1.2.4 Concerns over neonatal outcomes

In 1999 the Food and Drug Agency (FDA) in the USA issued a Public Health Notification, recommending caution when using a ventouse device for OVB (34), following 11 neonatal deaths and nine serious injuries arising from cerebral bleeds secondary to the use of ventouse devices in 1995 to 1998. This notice contained specific instructions on the training required to use such devices, the importance of communicating the use of the device to the receiving paediatric team, and the importance of monitoring babies delivered using such a device. Again, while there is no direct evidence that this advisory notice has affected the decision-making of individual obstetricians, it is likely to contribute to an atmosphere where the use of such a device is carefully considered prior to use.

1.4.1.3 OVB in LMICs

While OVB is underutilised in LMICs relative to HICs (36), it cannot be assumed that demand for OVB is the same in LMICs as in HICs. Several factors are present to a greater degree in LMICs which may reduce the rate of OVB. These include the greater mean parity of women in LMICs, as well as the frequent absence of electronic fetal monitoring (EFM), which removes or makes it more challenging for the healthcare provider to establish a diagnosis of presumed fetal compromise (49). Furthermore, in Latin America the relatively lower percentage of women who reach the second stage of labour (due to high Caesarean section rates) will reduce the proportion of women in whom an OVB might ever be indicated. However, despite these factors, given the relatively much higher rates of severe maternal and neonatal morbidity and mortality reported as a result of complications in the second stage of labour in LMICs relative to HICs (four to 13% of maternal deaths in Africa, Asia, Latin America and the Caribbean (5)), it seems reasonable to assume that there remains significant unmet demand for OVB in LMICs. Despite this likely increased demand, rates of OVB within LMICs are broadly lower than those in HICs (26).

In addition to the generally low absolute rates of OVB in Asian, African and Latin American countries reported by the WHO in 2010 (Africa 3%, Asia 3.2%, Americas 1.6%) (26), access to OVB is fragmented and reflects the varying levels of care available to women based on geographical relationship to care centres, with larger hospitals more likely to be able to perform OVB, and smaller clinics less likely. A majority of women in Sub-Saharan Africa may not have access to OVB at all when required – this was shown by a secondary analysis of unit-level survey data covering selected countries in Asia, Africa and Latin America from 2005 to 2015 by Bailey et al. This found that in sub-Saharan Africa OVB was recently performed in only 6% of non-hospital settings and 53% of hospitals. Although the absolute rates of availability were better in some other countries, the disparity in performance of OVB between hospitals and non-hospitals remained in almost all countries (i.e. Haiti 24% vs 3%, Bangladesh 52% vs 12%, Nepal 31% vs 5%) (50).

1.4.1.4 Drivers of low OVB rates in LMICs

Multiple factors have been postulated in the low rates of OVB in LMICs; lack of appropriate training in OVB techniques, lack of awareness of OVB as a suitable option for management of complications in the second stage of labour, and the utility of instruments used to perform OVB.

1.4.1.4.1 Lack of training

Skilled birth attendants (SBAs) should have the knowledge and skills required to perform straightforward OVBs (low and non-rotational) (51). However, it is well established that there are significant shortfalls in the availability of SBAs, and therefore the availability to provide effective emergency obstetric care, including OVB, worldwide (52). On this background of non-universal access to SBAs, Bailey et al. reported a lack of trained staff able to perform an OVB as the main reason for the inability of non-hospitals (and some hospitals) to perform OVB in seven countries out of 40 surveyed (notably this was the case in 72% of units in Cote d'Ivoire) (50). Furthermore, despite the WHO clearly stating that SBAs should be able to perform OVB, this is often not the case – multiple studies report lack of ability of SBAs (including non-certified attendants, midwives and doctors) to perform OVB as the main reason behind an inability to perform OVB in Latin American (57,58), sub-Saharan Africa (53,54) and Papua New Guinea (36).

1.4.1.4.2 Lack of awareness of indications for OVB

Given the low rates of utilisation of OVB within LMICs, it is unsurprising that some accoucheurs are unaware of the potential benefit. It is logical that such accoucheurs will not develop awareness of OVB themselves if they are trained in a setting where there are relatively few, if any experts who practice OVB. This is reflected in the literature - Bailey et al. found that six countries reported that the most common reason that a plurality of their health centres did not perform OVB was due to having no women in whom it was indicated (Laos, Cambodia, Bangladesh, Zambia, Benin & Haiti) (50).

Earlier surveys of practitioners in LMICs has demonstrated rates of non-awareness of ventouse delivery as high as 15% (27).

While this lack of awareness may be related to a lack of training in the utility of OVB, it may also reflect an informed reluctance to undertake a procedure which associated with substantially greater risk in LMICs than in HICs. For example, the relative risk of maternal death following OVB in all LMICs analysed as part of the WHO Global Survey on Maternal and Perinatal Heath (2004 to 2008) was 2.9 (95% CI 1.84 to 4.56), significantly higher than intrapartum Caesarean section performed with indications (RR 1.7, 95% CI 1.24 to 2.33) (26). Although this latter pool will include some women in the first stage of labour, generating results which are not directly comparable, the difference between the two may still be considered a useful marker for the significant morbidity and mortality associated with OVB in LMICs. This possible increase in risk of OVB in LMICs may be caused by multiple factors unrelated to the training level of the SBAs, such as poorer condition of women and babies at the time of presentation, poorer quality of available instruments and lack of appropriate aftercare.

1.4.1.4.3 Utility of instruments in LMICs

Instruments are required to perform OVB, and these require procurement, maintenance, sterilisation and training for practitioners to be able to use them effectively. At present, there is no device which has achieved a recognised superiority in any of these factors. Reusable ventouse devices, such as Malström cups and silastic ventouse, are prone to failure of the component parts, particularly leaking tubes or broken vacuum bottles, and require electricity to create a vacuum which can limit utility in LMICs (27). Forceps, while easy to maintain and effective in trained hands, are associated with higher rates of maternal trauma (11) and are regarded (perhaps erroneously) as requiring higher levels of training and expertise for use (49). The disposable single-use Kiwi ventouse (Clinical Innovations, Salt Lake City, Utah, USA) theoretically overcomes these challenges by not requiring the use of an electric pump, tubes or other vacuum equipment, not being associated with the higher rates of maternal trauma found with forceps. Moreover it is perceived as not requiring the levels of experience and training required in the use of forceps. However, despite these advantages, the provision of Kiwi ventouse alone has not been sufficient to increase OVB in LMICs to a level commensurate with likely demand.

The varying levels of utilisation of OVB between national settings suggests that, regardless of the material and personal issues which may restrict use, different maternal populations present with different clinical characteristics in labour, and this may partially explain some (but not all) of the variation in OVB rates. The clinical factors that may impact on the success or failure of OVB also need to be considered.

1.5 Characteristics of beneficial or harmful OVB

Relative to Caesarean section, operative vaginal birth can be beneficial or harmful to the woman and her baby depending on the clinical presentation, the setting, the skill of the operator, and the number of instruments used. More complex procedures, performed by less experienced members of staff and using a second instrument are in general more likely to be associated with poorer maternal and neonatal outcomes.

1.5.1 UK specific performance of OVB versus Caesarean section

In UK settings, OVB is likely to be beneficial compared to Caesarean section – Murphy et al. in 2001 found that in two UK units which modelled best practice at the time, and with skilled accoucheurs, immediate recourse to Caesarean section and the use of either forceps or ventouse dependent on operator choice, following Caesarean section women were more likely to have a major haemorrhage (>IL, RR 2.8) and extended hospital stay (>6 days, RR 3.5) and babies were more likely to be admitted to Neonatal Intensive Care (NICU) (RR 2.6) but less likely to sustain trauma (RR 0.4).

However, the characteristics of the settings of these studies are not universal and will have a real impact on maternal and neonatal outcomes following OVB.

1.5.2 Clinical factors

1.5.2.1 Position of the fetal head

Malposition of the fetal head in the second stage of labour was demonstrated by Senecal et al. to be associated with an increased risk of multiple adverse maternal and neonatal outcomes, including higher risks of postpartum haemorrhage (PPH), severe perineal tearing, need for oxytocin augmentation of labour, longer second stage of labour and Caesarean section, as well specifically higher rates of OVB (36.5% OVB rate for OA, 50.8% of OP) (55).

In addition Palatnik et al., in a retrospective cohort study of all attempted OVBs in one unit in the USA over 9 years (n = 4423), found that persistent malposition of the fetal head (any position other than direct OA, left occipito-anterior (LOA) or right occipito-anterior (ROA) is more likely to be associated with a failed OVB (RR 3.73) (56).

1.5.2.2 Progress of labour

OVB performed in a clinical setting with features of obstructed labour appears to be more likely to be associated with poorer maternal and neonatal outcomes than either OVB performed without these features present or Caesarean section. In a retrospective cohort study of all attempted mid-pelvic OVBs in British Columbia between 2004 to 2014 (n = 10901), OVBs births performed for a diagnosis of 'dystocia' were significantly more likely to be associated with severe maternal and neonatal morbidity compared to Caesarean section (severe maternal morbidity: CS RR 1.0, forceps RR 1.57, ventouse RR 2.29, severe neonatal morbidity: CS RR 1.0, forceps RR 2.11, ventouse RR 2.17). By comparison, rates of adverse maternal and neonatal outcomes were greater following attempted OVB when a diagnosis of dystocia was not present relative to CS, but these differences were either smaller or in favour of OVB (severe maternal morbidity: CS RR 1.0, forceps RR 2.34, ventouse RR 0.79, severe neonatal morbidity: CS RR 1.0, forceps 1.15, ventouse RR 1.28) (57).
Conversely, Ducarme et al., in a prospective study of 2138 women who underwent OVB, did not find any differences in outcomes for women or babies when stratified by station of the fetus in the pelvis (58). This would suggest that the negative predictive effect of obstruction cannot be determined solely through vertical progress through the pelvis, but rather is related to other factors which reflect the prospect of successful vaginal birth, such as oedema, haematuria, caput or moulding.

1.5.3 Accoucheur-dependent characteristics and associated outcomes

In addition to the clinical prognostic markers such as malposition and progress of labour, there are several operator-dependent factors that may influence the maternal and neonatal outcomes following an attempted OVB. These factors have the potential to be modified and therefore are of significance when considering strategies to improve outcomes following OVB.

1.5.3.1 Experience of the accoucheur

While several commentaries have suggested that better trained and more experienced accoucheurs are more likely to generate better maternal and neonatal outcomes following OVB (17,26), this has not been conclusively demonstrated in the literature. Recent reviews have examined the role of senior presence on labour ward on outcomes of all women (not specific to OVB). A recent systematic review of by Henderson et al. found that OVB was undertaken more frequently when consultants were present (RR 1.14), but was unable to comment on the maternal and neonatal outcomes of these births due to lack of consistent data (59). Furthermore, a separate systematic review and meta-analysis by Reid et al. of outcomes did not find any such difference, nor did it demonstrate any difference in clinical outcomes (although it examined outcomes of all women who passed through the units, not solely outcomes following OVB) (60). Therefore, although potentially desirable for other reasons, it has been recognised that senior presence alone does not necessarily improve outcomes for women and babies within the wider context of all maternity care. Although not examined in detail, this seems likely to be the same within OVB. Despite some small studies demonstrating differences in indirect markers of patient outcomes (superior rates of diagnosis of fetal position among more experienced accoucheurs (61), increased risk of junior accoucheurs attempting more than three pulls and use of multiple instruments (62), or better placement of forceps blades in simulated OVBs (63)) larger studies specifically looking at the effects of presence vs non-presence of senior clinicians at OVB have not shown a difference in maternal or neonatal outcomes (71,72). Moreover, other studies looking at the effect on outcomes of different techniques for OVB (not explicitly looking for the effect of senior presence) have found no difference in outcomes when outcomes are not adjusted for the presence of a senior clinician (21,64).

However, in most settings, junior accoucheurs are directly supervised during all attempted deliveries for at least the first two years of practice, as well as during more complicated procedures thereafter – this may (rightly) limit the exposure of true novices to situations where a lack of skill could result in a failed procedure, and thus be detected in any study. Moreover, experienced maternity practitioners (senior midwives) acknowledge that significant differences in skill between senior accoucheurs exist, and that some accoucheurs are more skilled at OVB than others, although the differences are hard to specify in a detailed manner (65,66). Therefore, it seems likely that there are differences in outcomes following OVB between skilled and non-skilled accoucheurs, but these have not yet been detected as no studies have stratified participants in this manner.

1.5.3.2 Number of instruments used

The use of more than one instrument in an attempt to perform OVB is associated with poorer maternal and neonatal outcomes. In a retrospective cohort study of 1360 OVBs performed in two hospitals in the UK in 2005 and 2006, Murphy et al. demonstrated that sequential use of instruments was associated with greater maternal and neonatal morbidity when compared to use of a single instrument (anal sphincter tear OR 2.1 (95% CI 1.2 to 3.3); umbilical artery pH <7.10 OR 3.3 (95% CI 1.7 to 6.2)). Furthermore, sequential instrument use had greater morbidity than use of forceps alone (anal sphincter tear OR 1.8 (95% CI 1.1 to 2.9); umbilical artery pH <7.10 OR 3.0 (95% CI 1.7 to 5.5)) (67). This finding has been replicated in studies examining different clinical presentations. A retrospective cohort study of all attempted mid-pelvic OVBs in British Columbia between 2004 to 2014 (n = 10901) found that rates of severe neonatal morbidity were higher following an attempted OVB using sequential instruments in a setting of dystocia than those following either Caesarean birth, forceps or ventouse alone (CS RR = 1, forceps RR = 2.11, ventouse RR = 2.17, sequential RR = 4.68) (57).

1.5.3.3 Placement of instruments

Instruments are designed to exert traction over a specific area of the fetal head to facilitate delivery (over the zygomatic arches in the case of forceps, and over the flexion point in the case of ventouse). Exertion of force over areas other than those intended is more likely to lead to fetal injury and/or failure to deliver. This is demonstrated in the only study examining maternal and neonatal outcomes relative to placement of instruments. In a prospective sample of 478 sequential attempted OVBs (both forceps and ventouse) in two units in Ireland, stratified into optimal and suboptimal placement, Ramphul et al. found that suboptimal placement was associated with prolonged hospital stay (OR 2.28, 95% CI 1.30 to 4.02), greater neonatal trauma (OR 4.25, 95% CI 1.85 to 9.72), a greater use of sequential instruments (OR 3.99, 95% CI 1.94 to 8.23) and caesarean section for failed instrumental delivery (OR 3.81, 95% CI 1.10 to 13.16) (64). While this supports the general notion that misplacement is associated with poorer outcomes, each instrument has specific adverse outcomes which may be more common following misplacement.

1.5.3.3.1 Misplacement of forceps

Obstetric forceps are capable of exerting a great deal of pressure directly onto the fetal skull (up to 309 Newtons (N)), dependent on the strength and size of the operator (68). Misplacement of forceps blades has been postulated as contributing to the significantly higher rates of depressed skull fracture found in a cohort of 68 French babies with depressed skull fractures delivered with forceps versus spontaneous births (69). Furthermore, placement of forceps blades over specific sensitive fetal structures can cause significant injury – placement over the eyes may lead to long-term corneal scarring (70).

1.5.3.3.2 Misplacement of ventouse

When correctly placed over the flexion point and traction is applied, the ventouse works by generating flexion of the fetal head. This causes the narrowest possible diameter of the fetal head (the suboccipito-bregmatic diameter) to present to the pelvic canal, facilitating an easier birth (36). Therefore, misplacement of a ventouse is more likely to be associated with a failed attempted OVB, as well as potentially requiring greater traction force to be applied. This was demonstrated in a sub-analysis of a small observational cohort study of outcomes associated with the use of the Kiwi ventouse in 119 sequential attempted OVBs in two units in Brisbane between 2001 and 2002. The most severe neonatal outcome observed was a subgaleal haemorrhage, and was sustained by a baby in which cup placement was both deflexing and paramedial, requiring a relatively high level of traction force to be applied over a longer than usual period of time (130 N over 17 minutes) (71).

1.5.3.4 Traction force applied with instruments

It is axiomatic that less traction force exerted upon a fetus will result in less potential trauma as a result of this force. Both forceps and ventouse demonstrate this relationship.

1.5.3.4.1 Traction force exerted with forceps

Forceps are capable of transmitting a great deal of traction. The transmission of a lower total force (by either the exertion of less traction or exerting traction over a shorter period of time) is likely to reduce the level of adverse maternal and neonatal outcomes generated. This is demonstrated in several studies which have examined the number of pulls used to deliver the baby. Although these have not measured the force applied, it is reasonable to assume that if the baby descends significantly with the first pull, the operator is likely to exert less force on subsequent pulls. Whereas if the baby advances slowly, the operator is likely to use equivalent or greater force on subsequent pulls, creating a situation in which as an operator uses an increasing number of pulls they also apply an increasing amount of force.

Murphy et al. demonstrated, in a retrospective cohort study of 390 women undergoing attempted OVB in theatre in two UK units between 1999 and 2000, that more than three pulls at attempted OVB was associated with increased neonatal trauma for both completed (OR 4.2, 95% CI 1.6 to 9.5) and failed deliveries (OR 7.2, 95% CI 2.1 to 24) (62). Similarly, in a small retrospective cohort study of 87 women who underwent sequential attempted OVB with forceps in one unit in Japan between 2012 and 2014, Matsumoto et al. demonstrated a statistically significant increased risk of neonatal facial injury after three pulls relative to one pull (OR 16, 95% CI 2.1 to 123.3, $p < 0.01$). There was no difference between one and two pulls (72).

1.5.3.4.2 Traction force exerted with ventouse

A similarly proportional relationship as that observed with forceps may exist with ventouse. This has been examined in two small, limited studies studying the correlation between the amount of traction force exerted with ventouse and subsequent maternal and neonatal outcomes. Vacca et al., in their cohort study of 119 sequential attempted OVBs using the Kiwi ventouse, found that deliveries completed with a traction force that never exceeded 115 N tended to be less likely to be associated with both neonatal scalp abrasion (RR 0.38, 95% CI 0.12 to 1.24) and cephalohaematoma (RR 0.34, 95% CI 0.08 to 1.41) relative to those that did not. However, neither of these associations were statistically significant. As all attempted OVBs were successful, no difference in success rate could be determined (71).

While this evidence is intuitive, the 100% success rate does not reflect rates found in recent UK-based studies (73,74).

In contrast, Hofmeyer et al. in a small, unblinded randomised controlled trial (RCT) of 31 women in Johannesburg in 1989 demonstrated that the rate of failure following the use of rigid mushroom cups (Bird's and O'Neil) was significantly lower than that found during the use of soft cups (OR 12.9, CIs 12.2 to 138). In this study, rigid cups were able to generate significantly higher levels of maximum traction force than soft cups (Silc and Silastic) (158 N vs 110 N). No differences were found in any of the markers of neonatal outcome, although these were limited to 1-minute Apgar < 8 and the appearance of the scalp 5 minutes after delivery (75).

Neither of these studies was sufficiently powered *a priori* to demonstrate a difference in maternal or neonatal outcomes. However, taken together the studies suggest that a more rigid cup (able to transmit greater traction force), is likely to increase the rate of injuries (cephalohaematoma and scalp abrasions) that are associated with the negative pressure generated by the ventouse. The corollary of this increased level of transmitted traction force may be a higher rate of successful delivery. What cannot be determined is to what extent the potential increased rate of vaginal birth outweighs the increased potential rate of neonatal complications.

1.5.3.5 Pressure exerted by instruments

Both forceps and ventouse exert pressure (forceps exerting positive pressure, ventouse exerting negative pressure) on the fetal head. Again, it is axiomatic that less pressure exerted will result in lower rates of complications. While no studies have prospectively quantified the pressures exerted by either forceps and ventouse and compared these to clinical outcomes, there is strong evidence that pressure exerted on the fetal head is the proximate cause of several significant adverse outcomes.

1.5.3.5.1 Positive pressure

Positive pressure (applied by forceps) can result in crush injuries to fragile facial structures. The following adverse outcomes are associated with forceps birth to a significantly greater degree than ventouse, suggesting that positive pressure plays an important role in their aetiology:

(i) Scalp/skin injuries (11)
(ii) Facial nerve palsy (76)
(iii) Ocular injury (77)
(iv) Skull fracture (69,78)

1.5.3.5.2 Negative pressure

Negative pressure over the fetal head can result in two separate types of injury – scalp injury and cerebral vascular injury. Scalp injuries result from where the cup adheres to the scalp and torsional force results in tearing or shearing of the fetal skin, or in severe cases, avulsion of the scalp (79).

Cerebral vascular injuries result from negative pressure exerted on the vascular network of the fetal skull, causing tearing of vessels and extravasation of blood. Cephalohaematoma, the most common form of injury, is usually mild and self-limiting (80,81). However negative pressure is more likely to be associated with subgaleal haemorrhage (SGA) than positive pressure. Estimates of absolute risk suggest rates of 0.44/1000 following spontaneous births, 1/1000 following forceps births and 5.9/1000 following ventouse (82,83). SGA occurs due to rupture of the emissary veins, and can result in up to 260ml of blood being extravasated into the subgaleal space, causing significant hypovolaemia, hypotension and, in extremis, coagulopathy and multi-organ failure (82,84). Mortality from SGA can be as high as of 25% of babies that are admitted to NICU due to SGA alone (85).

While there is speculation that softer and larger cups (capable of applying less traction and less pressure) may result in lower levels of SGA, no studies have assessed this theory directly, and the latest Cochrane review was unable to comment given the absence of any applicable data (11).

1.5.4 Instrument-dependent characteristics and associated outcomes

1.5.4.1 Diameter of instrument and fetal head

Greater diameters of the presenting fetal head/instrument may increase the rate of obstetric anal sphincter injury (OASI). This is demonstrated in differences in rate of OASI following ventouse and forceps (6.4% vs 22.7% respectively , without episiotomy) (86). This theory is supported by studies demonstrating that additional risk factors for OASI include greater fetal head diameter and birthweight (87).

1.6 Improving outcomes of OVB

Individual clinical and practitioner factors can be modified by patient selection and accoucheur training. These include placement of instruments, availability of supervision, communication and team working. Improvements in the performance of these skills by individual accoucheurs may facilitate better maternal and neonatal outcomes following attempted vaginal birth.

1.6.1 Placement of instruments

As previously discussed, correct placement of instruments will tend to reduce adverse events and increase success rates in OVB (73,78). Although several attempts have been made to design training programs to improve placement, none have so far been shown to impact on clinical outcomes. While computer simulation-based programs that track the movement of forceps blades and provide real-time feedback have been shown to improve the placement of forceps by junior accoucheurs in simulated OVBs (88), and 5-step Vacca technique of measuring and applying the Kiwi ventouse has been promoted by the RCOG (36), neither of these measures have been definitively associated with improvements in patient-level outcomes.

While it is reasonable to assume that thorough simulation training in OVB may improve instrument placement and thus clinical outcomes, more robust evaluation is required until this statement can be said to be evidence-based.

1.6.2 Availability of training, teaching and supervision

The presence of accoucheurs who are both clinically experienced in OVB and committed teachers can increase rates of OVB within individual settings (89). These improvements have been observed in a variety of settings. Solt et al. in one unit in the USA demonstrated that the addition of a dedicated OVB-positive senior accoucheur led to an increase in the rate of forceps birth by 59% over 2 years (2008 to 2010) (89). This has also been shown in a large

UK unit where the arrival of one experienced user of rotational forceps reduced the rate of Caesarean section at full dilatation by 20% over a four year period (2009 to 2013) (42). Significant improvements have also been seen in LMICs, where, following intensive training in the use of ventouse, rates of OVB increased substantially in settings as diverse as Ecuador (90) and rural Malawi (54).

Patterns of use of instruments for OVB have been modified by structuring routine training for junior obstetricians in a manner designed to prevent failure to acquire skills in methods of OVB that may be perceived as more challenging. This can be achieved by teaching junior accoucheurs the use of forceps prior to the use of ventouse. One such programme over four years in a large tertiary centre in Australia from 2010 to 2014 demonstrated an increase in the use of forceps (OR 1.5, 95% CIs 1.03 to 1.96) and a matching reduction in ventouse. However there was no significant change in maternal or neonatal clinical outcomes (91). While these case studies demonstrate that localised changes and in some cases improvements in OVB rates are possible, improvements often depend on the arrival of expert users who have already been trained in other units. While this is inevitably the only recourse individual units have at present, a more generalised increase in OVB rates (particularly in LMICs) is unlikely to be achieved in this manner alone (8,17,96). Local leadership may be more able to deliver sustainable improvements in outcomes – this approach has been demonstrated in previous studies implementing obstetric emergency skills training (92-94).

1.6.3 Communication with the patient and wider team

Women who have had an OVB are more likely to be dissatisfied with their birth experience compared to women who have had a spontaneous vaginal birth (95,96). This can lead to increased sexual dysfunction (97), aversion to subsequent pregnancies (98), and complaints and litigation (99,100). Cross-sectional surveys of women who have undergone OVB have identified the factors that promote a more positive experience by the woman undergoing OVB as:

- *Communication* “I felt well informed due to good communication”
- *Respect* “I felt I was treated with respect at all times”
- *Safety* “I felt safe at all times” (101)

While these factors have been identified, and are promoted through the current ROBuST simulation training package (36), there has not as yet been any evaluation as to how these factors can be promoted either within individual accoucheur-patient or wider team-patient interactions. At present best practice states that women should have the indication and purpose of any OVB clearly explained, be told what to expect both during and after the OVB, and thoroughly debriefed after the event (36). While this is likely to help promote good maternal perception, the impact of these recommendations has not been evaluated and so it is not possible to definitively say how the factors which could engender positive maternal perception can be promoted.

1.7 Promoting better management of complications in the second stage of labour

In light of the heavy burden of maternal and neonatal morbidity and mortality generated by complications in the second stage of labour, current management of these complications is axiomatically not satisfactory (3,5).

Complications in the second stage of labour will continue to occur and are likely to increase. Factors associated with a prolonged or complicated second stage of labour, such as nulliparity, maternal obesity, diabetes, increasing maternal age, use of regional analgesia and augmentation of labour with oxytocin are all increasing worldwide (102,103). Moreover, despite significant initiatives among professional and international bodies to reduce the rate of Caesarean section over the past 30 years (104,105), little progress has been made (106). This combination of rising complications, often poor availability of OVB and increased willingness to resort to Caesarean section represents a significant challenge to promoting the best possible maternal and neonatal outcomes in the second stage of labour.

In this context, increased provision of safe OVB has been identified as a possible solution to the problem of rising short and long-term complications (107). How to do so remains a matter of debate within the obstetric community. Any solution (particularly to be effective in LMICs) must overcome the challenges of potentially damaging instruments, the poor availability of expert teaching and the resource requirements of sterilisation and additional equipment (8,61).

1.7.1 Key features of any proposed new device

Any new device for OVB should incorporate features that improve its performance relative to current instruments for OVB. Specifically, it should be:

- Able to apply greater levels of traction than ventouse before failure
- Less potentially damaging to fetal and maternal tissues than forceps
- Require minimal or no ongoing support, such as electricity or sterilisation
- Able to be used by accoucheurs with both high and low familiarity with OVB (108)

1.7.2 The BD Odon Device

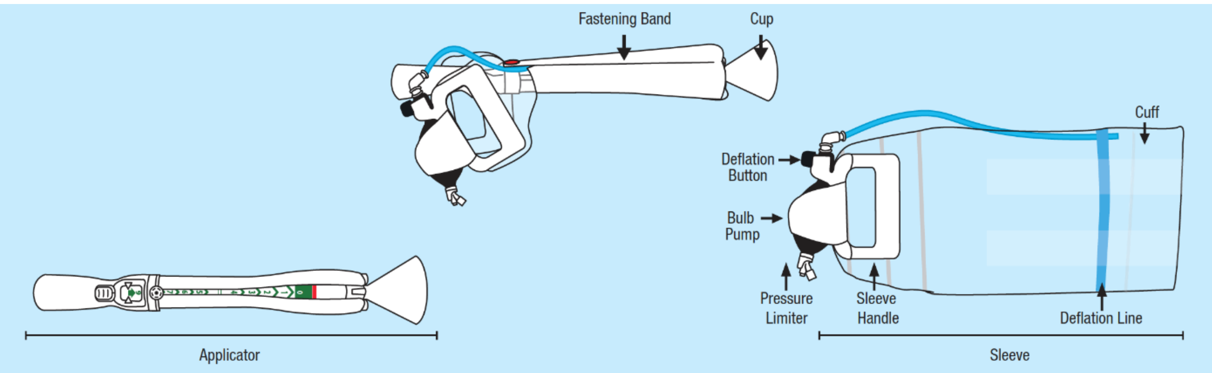
The BD Odon Device is a new device for OVB. It has been designed by a multi-professional team of engineers, doctors and midwives.

The design team believes that the device incorporates features that meet the challenges to any new device for OVB within the overall mechanism of the device.

1.7.2.1 Mechanism of the BD Odon Device

The device functions by placing an air cuff around the fetal head which is then used as a traction point to assist birth. The BD Odon Device consists of an applicator, sleeve and cuff, and fastening band (Figure 1-4).

Figure 1-4. BD Odon Device components



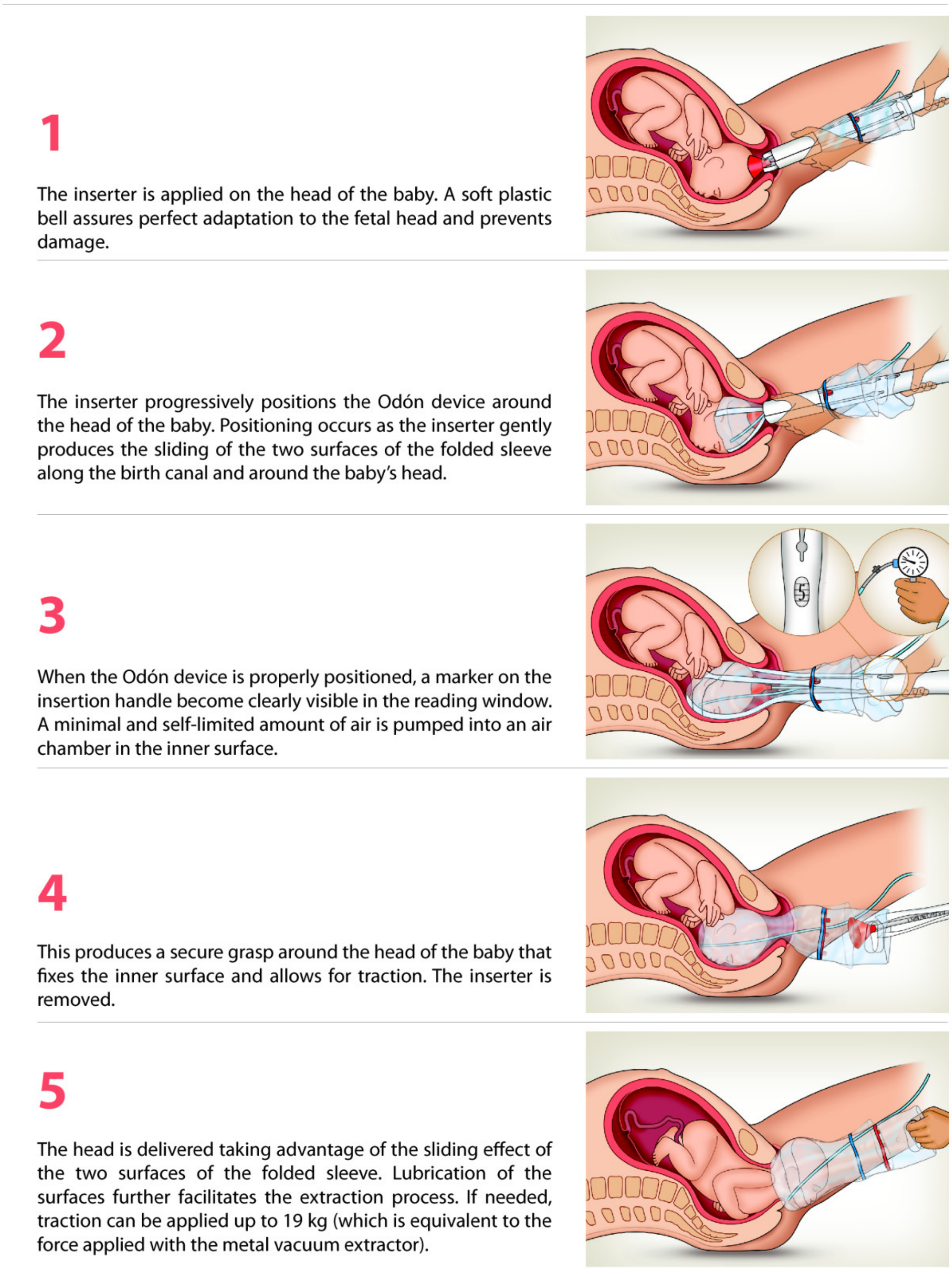
The applicator (four flexible spatulas emerging from an applicator handle) enables the operator to position the air cuff over the fetal head, past its widest point. The cup at the tip of the applicator facilitates the initial sliding motion of the cuff around the fetal head. The applicator is equipped with a progress indicator with markings allowing the user to check when the intended depth of insertion has been reached. The operator then inflates the air cuff using the hand pump. The cuff is equipped with a rapid deflation button enabling the operator to release the pressure at any point. The pump also includes a pressure valve, which prevents over-inflation of the air cuff.

Once the sleeve is situated over the fetal head, and the air cuff inflated, the applicator is removed by the operator. The air cuff is then re-inflated twice to compensate for a possible reduction in pressure.

The operator now grasps the handles of the sleeve and, following the J-shaped curve of the pelvis, applies traction with contractions to assist the birth of the fetal head. Just prior to crowning a blue “deflation line” will be visible past the introitus. At this point the operator deflates the cuff and continues to apply traction. Once the fetal head is born the cuff will spontaneously detach allowing the operator to continue to assist the birth of the baby.

This process is illustrated in Figure 1-5.

Figure 1-5. Visualisation of the use of the BD Odon Device



1.8 Evaluation of new devices

The aforementioned design features may, or may not, increase the clinical effectiveness of the BD Odon Device and reduce the burden of adverse outcomes on women and their babies. However, this can only be conclusively shown in a clinical evaluation of the device in the context of a randomised controlled trial comparing the device to the current most commonly used instrument. It is no longer acceptable to proceed directly to a clinical study for any new medical device without first undertaking a process where the design team seek to evaluate and improve the potential effectiveness and risk burden of the new device. The current relevant regulations form the European Union (Regulation (EU) 2017/757 – on medical devices, Annex I) states that manufacturers of medical devices should:

a) establish and document a risk management plan for each device;
b) identify and analyse the known and foreseeable hazards associated with each device;
c) estimate and evaluate the risks associated with, and occurring during, the intended use and during reasonably foreseeable misuse;
d) eliminate or control the risks … as far as possible through safe design and manufacture;
e) where appropriate, take adequate protection measures, including alarms if necessary, in relation to risks that cannot be eliminated; and
f) provide information for safety (warnings/precautions/contra-indications) and, where appropriate, training to users.

Moreover, "in eliminating or reducing risks related to use error, the manufacturer shall: reduce as far as possible the risks related to the ergonomic features of the device and the environment in which the device is intended to be used (design for patient safety), and give consideration to the technical knowledge, experience, education, training and use environment, where applicable, and the medical and physical conditions of intended users (design for lay, professional, disabled or other users)" (109).

Therefore, it is incumbent upon all design teams responsible for new medical devices to develop and utilise a methodology to identify, evaluate, quantify and enable, if possible, a reduction in risks through both design of the device and appropriate training of the intended users.

To date there have been no attempts to systematically evaluate and reduce the risks of a new medical device in operative vaginal birth.

1.8.1 Proposed methodology for evaluating risks of the BD Odon Device

Simulation has been established as a robust means of driving improvements within the wider field of obstetrics. Numerous studies have used simulation to teach and consolidate the practical and team-working skills of birth attendants, and have been associated with improvements in maternal and neonatal outcomes (92,110). Moreover, previous studies have used simulation methodology to improve operator performance at specific skills relevant to OVB, such as examination (111) or placement of forceps (88). While not yet demonstrated in literature, it is therefore reasonable to assume that information generated or operator behaviours learnt or refined during OVB simulations can be applied to in-vivo situations.

This thesis therefore sought to develop a methodological simulation-based approach to evaluating, and therefore reducing, the risks associated with OVB using a new device.

1.9 Primary objective of thesis

The primary objective of this thesis was to develop a simulation-based methodology for evaluating the risks of a new instrument (the BD Odon Device) for operative vaginal birth.

1.9.1 Hypothesis

It is possible to use simulation technology to prospectively quantify the likely characteristics of a new instrument for operative vaginal birth.

The specific aims of this thesis are to develop simulation methodologies for quantitatively describing the following characteristics:

1. Position of an instrument
2. Likely perineal trauma
3. Force generated by the instrument
4. Pressure generated by the instrument
5. Usability of the instrument by the intended operators

Chapter 2 Position of the BD Odon Device on a model fetal head

2.1 Abstract

Objective

To investigate the placement of the BD Odon Device on the model fetal head

Design

Observational simulation study

Setting

North Bristol NHS Trust, UK

Population or Sample

490 simulated operative vaginal births

Methods

Three bespoke fetal mannequins were developed to represent (i) bi-parietal diameter of the 50th centile at term (ii) bi-parietal diameter at the 5th centile at term and (iii) 50th centile head with 2 cm of caput. Siting of the BD Odon Device on model heads was determined before and after 490 simulated operative vaginal births. Variables were analysed to determine their effect on device siting and movement during birth.

The fetal mannequins were placed inside a maternal mannequin (PROMPT Flex, Limbs & Things, Bristol, UK) and the BD Odon Device was placed around the fetal head as per the instructions for use. The location of the air cuff was determined before and after the head was delivered.

Main Outcome Measures

Site and displacement during birth of the BD Odon Device on a model head.

Results

The BD Odon Device was reliably sited in a standard over the fetal head position (approximately 40mm above the fetal chin) for all stations, head sizes and positions with no significant displacement. In occipito-posterior births, compared to occipito-anterior or transverse, the BD Odon Device routinely sited further down the fetal head (toward the chin).

Conclusions

Chapter 2 - Position of the BD Odon Device on a model fetal head

The BD Odon Device behaves in a repeatable and reliable way in citing over the fetal head in 490 simulated births representative of clinical practice.

2.2 Introduction

Any potential new instrument for operative vaginal birth must be carefully evaluated for safety and efficacy. An ideal instrument should be associated with minimal risks to the mother and her baby, have a low failure rate, be simple to use and finally, be acceptable to both women and medical practitioners.

Instruments should be able to be reliably sited over the intended area of the fetal head. Instruments are designed to transmit mechanical force to the fetal head in order to expedite the passage of the fetus through the birth canal, and the application of this force onto the fetal head should be carefully controlled. Sub-optimal placement of instruments, either forceps or ventouse, is associated with both increased levels of harm and injury, as well as lower levels of successful birth (64,71). The drivers of suboptimal placement are; i) incorrect diagnosis of position and ii) inaccurate placement of instrument even when the position has been correctly diagnosed. Both of these causes and subsequently poor placement, are common.

Incorrect diagnosis of position has been found to occur in 20 to 44% of cases in reported UK-based studies (61,112). In addition, sub-optimal placement has been found in as many as 40% of retrospectively analysed ventouse deliveries (113) and 62% of simulated forceps deliveries (63).

Given that sub-optimal placement is both harmful and relatively common, it is important that any new instrument has a high degree of internal placement reliability. This means that it will, due to its inherent design features, reliably sit over the intended area of the fetal head if used correctly. While misplacement due to factors such as incorrect position diagnosis or insufficient training can be mitigated by improving the clinical skills of the user population, any device should be able to be used repeatable and reliably in well-trained hands. There should be as little variation as possible in device performance due to the device itself, given the wide spectrum of placement possible due to user error. Moreover, the behaviour of the device in various expected clinical circumstances (OT or OP position, high or low station, presence of caput, variation in head size) should be properly understood and described. This may ensure that the device behaves as expected, and can therefore be used, in almost any clinical situation. Furthermore, should it be found that the device is ineffective or behaves in a manner likely to result in harm in any particular clinical circumstance (i.e. face presentation, on a small head etc.), this should be formally recorded and incorporated into the instructions for the device.

The BD Odon Device is presently in development and offers a potential alternative to obstetric forceps and ventouse. The BD Odon Device consists of an inflatable circular air cuff attached to a thin circumferential polyethylene sleeve. A semi-rigid plastic applicator is used to place the air cuff and sleeve into the birth canal, past the widest diameter of the fetal head. The air cuff is inflated around the fetal head, and the applicator is removed. During maternal contractions the accoucheur applies traction to the polyethylene sleeve, to assist birth of the baby.

The air cuff provides the traction anchor point of the BD Odon Device, and is intended to sit in a 'safe zone', between the fetal chin and nose anteriorly, and at the nape of the neck posteriorly. We sought to determine where the cuff sits in relation to sensitive fetal anatomy (neck, nose and eyes) in simulated births. In particular, this study investigated the effect on the position of the air cuff in relation to: (i) fetal position, (ii) fetal station, (iii) fetal head size, (iv) presence of caput succedaneum, and (v) the inflation pressure of the air cuff.

2.3 Methods

2.3.1 Development of fetal mannequins

The PROMPT birthing simulator (Limbs & Things, Bristol, UK) fetal mannequin was used. This mannequin has an average size head for a term fetus with a bi-parietal diameter (BPD) of 96mm, comparable to the 50th centile of 97mm at 39 to 40 weeks gestation (12) (Figure 2-1).

Figure 2-1. Model fetal head with biparietal diameter of 96mm

Two additional fetal mannequins were developed for use in this study. A new fetal model was manufactured with a BPD of 89mm, equivalent to a fetal head on the 5th centile (12) (Figure 2-2) to assess the risk of the device slipping onto and constricting the fetal neck in cases of a small head size. A second fetal mannequin was developed to simulate a 50th centile term fetus with a 2cm depth of caput succedaneum (situated in the midline between the anterior fontanelle and 2cm posterior of the posterior fontanelle) (Figure 2-3) to assess how the presence of caput succedaneum could affect the application and use of the BD Odon Device.

Figure 2-2. Model fetal head with biparietal diameter of 89mm

Figure 2-3. Model fetal head with 2cm of caput

2.3.2 Simulation of operative vaginal births

The pre-existing PROMPT birthing simulator fetal mannequin together with the two bespoke fetal mannequins were used with a PROMPT Flex maternal mannequin birthing simulator for the simulated operative vaginal births. All simulated OVBs were conducted by a single operator (SO'B).

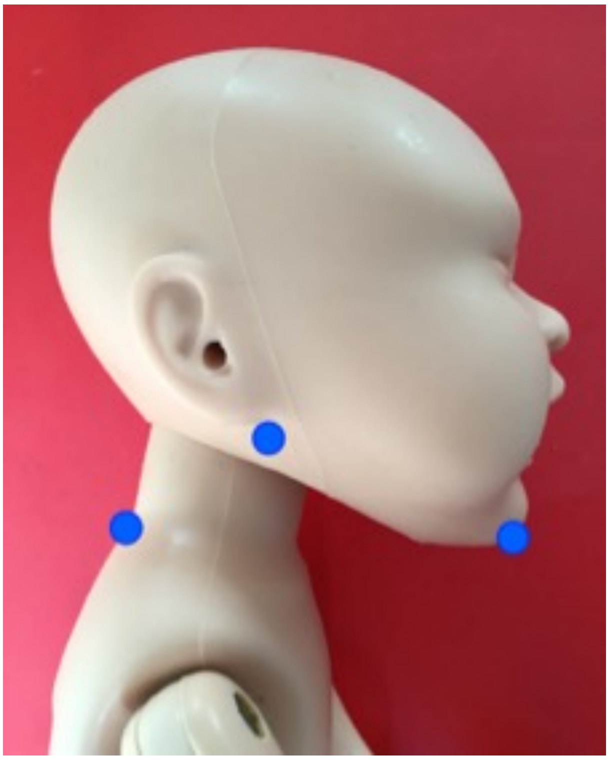
Four hundred and ninety simulated OVBs were performed to investigate the placement of the BD Odon Device and the effect of key variables on the position and movement of the BD Odon Device air cuff during simulated birth, namely:

1. fetal head size: 50^{th} centile, 5^{th} centile
2. presence of caput succedaneum
3. fetal position (occipito-anterior (OA), occipito-posterior (OP), right occipito-transverse (ROT), face presentation)
4. fetal station: vertex at the ischial spines, vertex 1cm below the ischial spines, vertex 2cm below the ischial spines
5. BD Odon device air cuff inflation pressure: 40kPa, 60kPa, 80kPa.

The range of BD Odon Device cuff inflation pressures tested (40 to 80kPa) is the range envisaged to be used in vivo. The behaviour of the device at pressures over 80kPa were not investigated. The device incorporates a pressure limiter which prevents the generation of inflation pressures greater than 80kPa.

During each simulated OVB, a modified procedure for using the BD Odon Device was employed. The air cuff was inflated and the applicator was removed. The distance of the inferior edge of the air cuff from four reference points on the fetal head ((i) mental protuberance (ii) right angle of mandible (iii) left angle of mandible and (iv) C7 posteriorly) was then measured in mm using a manual ruler (see Figure 2-4). Routine traction was applied in the standard manner to the BD Odon device sleeve to assist the birth of the fetal head. After crowning of the head, the air cuff should be deflated. However, in our modified procedure to ensure the position of the air cuff after traction had been applied to deliver the fetal head, the air cuff was left inflated and measurement of the distance between the air cuff from the fixed reference points on the fetal head was repeated.

Figure 2-4. reference locations for measurement of device position



Device placement data were collected: site of the device on a model head before birth, distance moved by the device over the model head during the simulated birth (mm), and site of the device on the fetal head post birth. All positions were determined relative to four reference points: the fetal mental protuberance, right angle of mandible (RAoM), left angle of mandible (LAoM) and C7 posteriorly. The data measuring distance from the mental protuberance and C7 were analysed as separate outcomes, whilst data from RAoM and LAoM were pooled to give a composite measure of device movement around the lateral aspects of the fetal head. Distances and displacement are reported as positive if the air cuff was sited or moved cephalad relative to the reference point (i.e. closer to the fetal vertex), and negative if the air cuff was sited or moved caudal relative to the reference point (i.e. closer to the fetal chin).

Results are provided for the location of the device on the model fetal head relative to fetal mental protuberance (Table 2-2) and relative to C7 (Table 2-4) before and after birth in scenarios where only one variable has changed (i.e. inflation pressure or head size or position or station).

Statistical analyses of the significance of degree of change in position of the device before and after birth relative to the mentum between all variable groups relative to a baseline group (BD Odon Device, 40kPa inflation pressure, OA, station +2, 50^{th} centile head size, no caput) are presented in Table 2-3.

Data describing differences in degree of movement of the device over the model fetal face from before to after birth between variable groups were analysed using a Kruskal-Wallis test. Bonferroni corrected p-values were derived to account for test-multiplicity. A p-value ≤0.05 was considered as evidence of group difference.
Analyses were conducted using Stata software, version 13 (StataCorp, College Station, Texas, USA).

2.4 Results

Four hundred and ninety simulated OVBs were performed. The number of births for each combination of variables is provided in Table 2-1. Selected results demonstrating the relative effect of the alteration of a single variable are presented in Table 2-2, Table 2-3 and Table 2-4. Data are presented as medians with quartiles, as they were not normally distributed (assessed using simultaneously Kurtosis statistics and the coefficient of skewness of the variable distribution as well as the qq plot and pp plot of this distribution). Full results of all 490 simulated births are given in Appendix 1.

Table 2-1. Numbers of births for each combination of variables

		Number of simulated births						
OA		**40 kPa**		**60 kPa**		**80 kPa**		**Total births**
		No Caput	**Caput**	**No Caput**	**Caput**	**No Caput**	**Caput**	
Spines	**Normal**	10	10	10	10	10	10	**60**
+2	**Small**	10		10		10		**30**
Spines	**Normal**	10		10				**20**
+1	**Small**	10						**10**
At	**Normal**	10	10	10	10	10	10	**60**
spines	**Small**	10		10		10		**30**
OP								
Spines	**Normal**	10	10	10		10		**40**
+2	**Small**	10						**10**
Spines	**Normal**	10		10				**20**
+1	**Small**	10						**10**
At	**Normal**	10		10		10		**30**
spines	**Small**	10						**10**
ROT								
Spines	**Normal**	10	10	10		10		**40**
+2	**Small**	10						**10**
Spines	**Normal**	10		10				**20**
+1	**Small**	10						**10**
At	**Normal**	10		10		10		**30**
spines	**Small**	10						**10**
Face								
Spines	**Normal**	10		10		10		**30**
+2	**Small**	10						**10**
Spines	**Normal**							
+1	**Small**							
At	**Normal**							
spines	**Small**							
							Total births	**490**

2.4.1 Location of air cuff in relation of the fetal chin

Prior to the application of traction, the inferior edge of the BD Odon Device air cuff was positioned on, or above, the fetal mental protuberance (i.e. between the fetal chin and nose) in all simulations. In all 490 simulations performed prior to the application of traction to the BD Odon Device the median distance between the inferior edge of the BD Odon Device air cuff and the fetal mental protuberance was 40mm (1st and 3rd quartiles [Q1, Q3], 21mm & 45mm).

The inflation pressure within the air cuff had little effect on the initial position of the device from the fetal chin: 43mm [40 to 44.5], 46mm [43.5 to 46.5] and 44.5mm [41 to 46] for inflation pressures of 40, 60 and 80kPa respectively.

The ROT position, presence of caput, 5th centile head size and vertex at station +1cm below ischial spines had little effect on the position of the device relative to the fetal chin: 44mm [41.7 to 48], 44.5mm [42 to 50.5], 37mm [33 to 38.5] and 44mm [42 to 44.5] respectively. On average the air cuff moved less than 10mm in either direction during birth.

However, the air cuff was located lower on the fetal face (nearer the chin) when the fetus was in the OP position (median distance to chin 31mm [25 to 36.5] before birth, and was noted to be beneath the fetal chin after birth in the majority of cases (median distance to chin -10mm [-12 to -6]). The air cuff moved by a greater margin in these OP simulations, on average moving down the fetal face (toward the chin) by 36mm during birth [-47.5 to 30.5].

In births where the model fetus was at the level of the ischial spines, the air cuff moved by 9.5mm during birth. This is due to the air cuff being placed higher (toward the vertex) on the fetal head before birth than in any other scenario, 49.5mm [45.7 to 74] above the fetal chin. In these scenarios the air cuff was located in a similar site on the fetal head to procedures in OA or OT positions after birth, 42mm [39 to 44.5] above the fetal chin.

These results are shown in Table 2-2.

Ten attempts were made to apply the BD Odon Device in a mento-anterior face presentation, although this would be an unlikely circumstance in clinical practice. The BD Odon Device spontaneously slipped off the face during inflation in three (30%) of these attempts. These findings confirm that it is inappropriate to use the BD Odon Device for face presentations.

Testing for statistically significant differences revealed that each chosen variable (inflation pressure, position, station) was not sufficient in itself to generate significant difference in the distance of the cuff from the mentum, relative to the reference group (OA, +2 spines, 50^{th} centile head, 40 kPa inflation pressure, no caput), with the exception of the addition of caput and the use of a small head. This is shown in Table 2-3.

Table 2-2. Placement of BD Odon Device in relation to the mental protuberance

	Variable								
Fetal head size (term BPD centile)	50th	50th	50th	50th	50th	50th	5th	50th	50th
Position	OA	OA	OA	ROT	OP	OA	OA	OA	OA
Caput present	No	No	No	No	No	Yes	No	No	No
Inflation pressure of BD Odon Device cuff (kPa)	40	60	80	40	40	40	40	40	40
Station (cm below ischial spines)	+2	+2	+2	+2	+2	+2	+2	+1	0
Number of births (n)	10	10	10	10	10	10	10	10	10
Before birth median distance from mental protuberance in mm (Q1, Q3)	43 (40 to 45)	46 (44 to 47)	45 (41 to 46)	44 (42 to 48)	31 (25 to 37)	45 (42 to 51)	37 (33 to 39)	44 (42 to 45)	50 (46 to 74)
After birth median distance from mental protuberance in mm (Q1, Q3)	42 (40 to 43)	43 (42 to 44)	41.5 (-23 to 44)	40 (36 to 43)	-10 (-12 to -6)	40 (40 to 45)	39 (26 to 40)	44 (42 to 44)	42 (39 to 45)
Before-after birth median change in mm (Q1, Q3)	-5 (-8 to -2)	-4 (-5 to 0)	-3 (-60 to 0)	-5 (-23 to -2)	-36 (-48 to -31)	-5 (-8 to -2)	0 (-8 to 4)	-1 (-4 to 1)	-10 (-29 to -3)

Table 2-3. Degree of movement of BD Odon Device in relation to mentum from before to after birth between single variable groups across all births

	Variable (s)						
Variable	**Baseline group ***	**60kPa inflation pressure**	**80kPa inflation pressure**	**ROT position**	**OP position**	**Caput present**	**5th centile head size**
Number of births (n)	30	80	80	90	90	80	130
Before birth median distance from mentum in mm (Q1, Q3)	44 (42 to 48)	44 (19 to 46)	42 (5 to 45)	44 (40 to 48)	16 (0 to 28)	46 (42 to 48)	20 (4 to 35)
After birth median distance from mentum in mm (Q1, Q3)	42 (40 to 44)	40 (-16 to 44)	40 (-20 to 44)	42 (38 to 45)	-12 (-24, to 35)	42 (40 to 45)	-14 (-20 to 38)
Before-after birth median change (Q1, Q3)	-4 (-9 to 0)	-6 (-17 to -1)	-4 (-20 to 0)	0 (-4 to 0)	-25 (-38 to -2)	-3 (-6 to 0)	-16 (-29 to 0)
Significance of before-after birth change from reference group (p)		0.47	0.47	0.23	0.01	0.96	0.03

*Baseline group: 50th centile head, OA, no caput, 40kPa inflation pressure, +2 station

2.4.2 Location of air cuff in relation to the fetal 7th cervical vertebrae (C7):

All variables, except the OP position, had little effect on the position of the BD Odon Device air cuff relative to the 7th cervical vertebrae (C7): for all variables except OP position, the air cuff was located within 15mm of C7, and moved less than 10mm from before to after birth. In the OP positions, the air cuff was consistently sited higher up the fetal head, towards the vertex (26mm, [15 to 29]). During birth it moved down the fetal head by 23mm [-29.5 to -17.5] so that it was located just below C7, with a median distance from C7 of -2mm [-2.5 to 0.5]

These data are presented in Table 2-4.

Table 2-4. Placement of the BD Odon Device in relation to C7

	Variable (s)								
Fetal head size (term BPD centile)	50^{th}	50^{th}	50^{th}	50^{th}	50^{th}	50^{th}	5^{th}	50^{th}	50^{th}
Position	OA	OA	OA	ROT	OP	OA	OA	OA	OA
Caput present	No	No	No	No	No	Yes	No	No	No
Inflation pressure of BD Odon Device cuff (kPa)	40	60	80	40	40	40	40	40	40
Station (cm below ischial spines)	+2	+2	+2	+2	+2	+2	+2	+1	0
Number of births (n)	10	10	10	10	10	10	10	10	10
Before birth median distance from C7 in mm (Q1, Q3)	-1 (-2 to 1)	5.5 (4 to 11)	4 (2 to 7)	14.5 (10 to 19)	26 (15 to 29)	10 (9 to 12)	9.5 (6 to 11)	0 (-1 to 0.8)	7 (4 to 18)
After birth median distance from C7 in mm (Q1, Q3)	0 (-12 to 1)	2.5 (0 to 5)	1 (-1 to 3)	8 (5 to 9)	-2 (-3 to 1)	13 (9 to 15)	9 (7 to 15)	0 (0 to 2)	7 (2 to 10)
Before-after birth median change in mm (Q1, Q3)	2 (-2 to 5)	-4 (-6 to -2)	-4 (-6 to 0)	-7 (-15 to -3)	-23 (-30 to -18)	2 (-2 to 5)	1.5 (-2 to 6)	0 (1 to 2)	-4 (-9 to 3)

2.5 Discussion

2.5.1 Main Findings

Using the standard operating procedure for placement, the BD Odon Device was consistently sited over the same area of the fetal head for all fetal head sizes, stations and positions, except OP and when the vertex was at the level of the ischial spines. For all other scenarios tested, the BD Odon Device was sited around the fetal head within 15mm of the level of C7 posteriorly, and between 37mm and 46mm above the fetal chin anteriorly (Figure 2-5). This is the same level as the tips of correctly applied forceps blades. Furthermore, the device was stable with minimal movement of the device (<10 mm) during simulated birth.

Figure 2-5. Typical location of the BD Odon Device on a model fetal head - 40mm above the fetal chin and 10mm above C7

In OP positions, the placement of the air cuff of the BD Odon Device was further down the fetal head, typically sited more cephalad (toward the vertex) over the posterior aspect of the neck, and more caudal (toward the chin) over the chin anteriorly when compared with births in an OA position. This may be a desirable feature, as deflexion of the fetal head is frequently associated with OP positions, and during inflation the BD Odon Device air cuff generated flexion of the fetal head. Increased flexion of the fetal head was observed in all positions, which may partially explain the mechanism of action of the device.

A significant hypothetical risk of the BD Odon Device was the possibility of the device slipping onto, and subsequently constricting the fetal neck. However, we observed that even when the device appeared to slip below the fetal chin, the downward traction on the device caused the cuff to only exert pressure on the inferior aspect of the mandibles, rather than on the anterior aspect of the fetal neck.

The location of the BD Odon Device was different in births performed with the vertex at the level of the ischial spines. In these births, the device was initially sited further cephalad (toward the vertex) than usual (49.5mm from the mental protubence, Table 2-2). After traction, the device was sited at the same level as other procedures, (42mm above the fetal chin). After the application of traction the BD Odon Device moves to the same site irrespective of the initial fetal station.

The BD Odon Device consists of an air cuff which, once inflated, is relatively incompressible. If the air cuff is further compressed (by an external force or by an increase in the intrinsic air pressure using the hand pump), the cuff will move to an area of lower external pressure. Because the fetal head progressively narrows between the widest point at the parietal ridge and the chin, an increase in pressure will result in the cuff to moving caudally (toward the chin). However, the anterior surface of the face between the nose and the chin is relatively flat, meaning that the cuff is likely to come to rest here rather than continue to travel caudally down the face. This observation was most pronounced in the births conducted with the vertex at the level of the ischial spines. The cuff initially is located higher towards the vertex. However, as traction force is applied, the air cuff moves caudally down the fetal head, coming to rest on the relatively flat portion of the face between the nose and chin.

The BD Odon Device was reliably sited in a “safe area” between the fetal chin and nose, for all the investigated fetal positions and stations.

2.5.2 Strengths and Limitations

This is the first study to prospectively investigate the performance of a novel device for operative vaginal birth using simulation. We employed a simulation methodology previously used to investigate and improve management of other areas of intra-partum care (110,114-116).

All simulations were performed by a single operator, which assisted internal consistency of measurement and eliminated inter-operator variability. However, we recognise the inherent limitations of this strategy, in particular the possibility of repeated systematic error.
We looked at the behaviour of the BD Odon Device with an average-sized head, a small head and a head with 2cm of caput. We did not analyse the behaviour of the BD Odon Device when used with a large head (i.e. >95th centile). As this was a 'worst-case scenario' simulation, we sought to evaluate the greatest perceived risk, the risk of the deice slipping over and constricting the neck. Due to the wider presenting part of a large head, we felt this risk to be less with a large head compared to a small head. Therefore, given the limited resources of the study, we only analysed the behaviour of the device with a small head.
Lubrication was used in our simulations – this would reflect real-world practice and we do not consider it to be a weakness of the study.
A further potential criticism of this study is the uncertainty whether our findings are generalisable to actual use of the device in clinical practice – while we acknowledge that this may be eventually discovered to be the case, the use of simulation models to predict instrument placement is already widely used and validated in teaching practice (63,88), and so it seems unlikely that utilisation of a similar model would not be consistent with clinical reality.

2.5.3 Interpretation (in light of other evidence)

Studies of ventouse and forceps have demonstrated that poor device positioning increases the risk of adverse outcomes (64,71). While correct positioning can be successfully taught (88), an instrument that can be reliably sited is an important safety feature. Our study demonstrates a high degree of concordance in the siting of the BD Odon Device across a wide range of fetal positions and stations.

2.6 Conclusions

In 490 simulations, using a robust and validated model, the BD Odon Device is consistently and reliably sited over the fetal head, and the location of the air cuff on the fetal head is likely to be safe in clinical practice. The device does not appear to slip or move significantly during simulated births, and generates a degree of head flexion.

Inflation of the air chamber results in flexion of the fetal head which may be associated with an increase in efficacy of the device when compared to ventouse.

Appendix 1 Full results of all simulated births

2.7 Results not presented here

10 assisted births were attempted using the small head in FMA position, +2 at 40 kPa and FMA, +2 at 80 kPa. However, during this series of assisted births, it was not possible to apply the device in a manner that would allow the device to remain on the fetal head during and after inflation on 8 occasions in each presentation. Therefore no numeric results are presented for this series of births.

2.8 Results of simulations performed with 50th centile head

Table 2-5. OA, +2, 40 kPa

Reference point	Mean distance from reference point (mm) (range) [standard deviation]					
	Post inflation, pre birth n= 10			Post birth n= 10		
Mentum	43.0	(40 to 48)	[2.7]	40.4	(24 to 47)	[6.1]
RAoM	-15.6	(-20 to -5)	[5.2]	-17.0	(-20 to -10)	[3.0]
LAoM	-16.3	(-22 to -6)	[4.9]	-16.1	(-20 to 3)	[6.8]
C7	-0.7	(-4 to 2)	[2.1]	0.5	(-3 to 10)	[3.6]

Table 2-6. OA, +2, 60 kPa

Reference point	Mean distance from reference point (mm) (range) [standard deviation]					
	Post inflation, pre birth n= 10			Post birth n= 10		
Mentum	45.5	(40 to 52)	[3.2]	42.6	(40 to 45)	[1.7]
RAoM	-11.9	(-18 to -4)	[4.9]	-15.2	(-20 to -6)	[4.1]
LAoM	-11.3	(-19 to -4)	[4.4]	-12.7	(-19 to -4)	[3.9]
C7	6.6	(3 to 11)	[3.2]	2.7	(0 to 6)	[2.4]

Table 2-7. OA, +2, 80 kPa

Reference point	Mean distance from reference point (mm) (range) [standard deviation]					
	Post inflation, pre birth n= 10			Post birth n= 10		
Mentum	43.1	(36 to 46)	[3.5]	22.5	(-28 to 46)	[32.6]
RAoM	-19.4	(-30 to -9)	[6.4]	-28.4	(-38 to -16)	[7.5]
LAoM	-15.8	(-24 to -8)	[6.2]	-28.7	(-40 to -9)	[9.9]
C7	4.4	(2 to 8)	[2.5]	1.0	(-4 to 6)	[2.9]

Table 2-8. OA, +1, 40 kPa

Reference point	Mean distance from reference point (mm) (range) [standard deviation]					
	Post inflation, pre birth n= 10			Post birth n= 10		
Mentum	45.8	(42 to 66)	[7.2]	42.9	(38 to 46)	[2.4]
RAoM	-11.9	(-17 to 10)	[8.3]	-14.1	(-18 to -2)	[4.7]
LAoM	-14.9	(-20 to 5)	[7.3]	-15	(-18 to -6)	[3.7]
C7	1.6	(-2 to 18)	[5.9]	1.2	(0 to 7)	[2.4]

Table 2-9. OA, +1, 60 kPa

Reference point	Mean distance from reference point (mm) (range) [standard deviation]					
	Post inflation, pre birth n= 10			Post birth n= 10		
Mentum	37.8	(4 to 48)	[12.3]	43.4	(40 to 46)	[1.6]
RAoM	-18.6	(-20 to -16)	[1.3]	-15.8	(-28 to 16)	[11.7]
LAoM	-21.6	(-28 to -18)	[3.4]	-20.7	(-26 to -16)	[3.8]
C7	-0.1	(-4 to 4)	[2.1]	-0.5	(-4 to 2)	[1.6]

Table 2-10. OA, at spines, 40 kPa

Reference point	Mean distance from reference point (mm) (range) [standard deviation]					
	Post inflation, pre birth n= 10			Post birth n= 10		
Mentum	59	(44 to 90)	[17]	43.5	(32 to 71)	[10.4]
RAoM	-0.3	(-12 to 16)	[9.9]	-3.1	(-12 to 13)	[7.6]
LAoM	0.9	(-14 to 18)	[11.8]	-2.4	(-12 to 14)	[7.2]
C7	9.5	(2 to 20)	[6.8]	6.3	(0 to 14)	[4.5]

Table 2-11. OA, at spines, 60 kPa

Reference point	Mean distance from reference point (mm) (range) [standard deviation]					
	Post inflation, pre birth n= 10			Post birth n= 9		
Mentum	43.7	(39 to 49)	[3.0]	43.1	(39 to 45)	[2.2]
RAoM	-13.9	(-18 to -6)	[4.0]	-15.4	(-20 to -10)	[3.2]
LAoM	-14.8	(-19 to -8)	[4.3]	-14.1	(-20 to -6)	[4.6]
C7	4.8	(1 to 11)	[3.6]	1.5	(0 to 5)	[1.6]

During this series of births there was one instance of detachment of air tube from the cuff after inflation.

Table 2-12. OA, at spines, 80 kPa

Reference point	Mean distance from reference point (mm) (range) [standard deviation]					
	Post inflation, pre birth n= 10			Post birth n= 10		
Mentum	38.9	(29 to 47)	[6.0]	29.9	(-20 to 44)	[23.8]
RAoM	-19.3	(-28 to -9)	[5.2]	-22.8	(-45 to -8)	[12.0]
LAoM	-16.1	(-24 to -2)	[6.7]	-21.3	(-48 to -2)	[14.4]
C7	6.6	(-2 to 14)	[6.1]	2.0	(-4 to 12)	[4.8]

Table 2-13. OP, +2, 40 kPa

	Mean distance from reference point (mm)

Reference point	(range) [standard deviation]					
	Post inflation, pre birth n= 10			Post birth n= 10		
Mentum	30.5	(16 to 42)	[7.8]	-5.4	(-20 to 36)	[15.3]
RAoM	-9.0	(-26 to 4)	[9.1]	-28.0	(-36 to -14)	[6.0]
LAoM	-5.8	(-18 to 2)	[6.3]	-25.4	(-34 to 14)	[5.4]
C7	-22.6	(10 to 32)	[8.0]	-1.2	(-6 to 4)	[2.9]

Table 2-14. OP, +2, 60 kPa

Reference point	Mean distance from reference point (mm) (range) [standard deviation]					
	Post inflation, pre birth n= 10			Post birth n= 10		
Mentum	25.2	(18 to 32)	[5.9]	-14.8	(-18 to 26)	[14.6]
RAoM	-18.2	(-24 to -10)	[4.6]	-39.8	(-44 to -28)	[4.5]
LAoM	-17	(-24 to -10)	[4.1]	-33.1	(-45 to -24)	[6.5]
C7	20	(16 to 26)	[3.5]	-6.6	(-12 to 4)	[4.4]

Table 2-15. OP, +2, 80 kPa

Reference point	Mean distance from reference point (mm) (range) [standard deviation]					
	Post inflation, pre birth n= 10			Post birth n= 10		
Mentum	20.3	(8 to 30)	[6.9]	-24	(-30 to -12)	[5.4]
RAoM	-26	(-30 to -18)	[5.5]	-42.9	(-55 to -30)	[7.4]
LAoM	-24.6	(-32 to -14)	[5.3]	-38	(-50 to -28)	[6.2]
C7	9	(4 to 16)	[4.1]	-6.6	(-10 to 0)	[3.1]

Table 2-16. OP, +1, 40 kPa

Reference point	Mean distance from reference point (mm) (range) [standard deviation]					
	Post inflation, pre birth n= 10			Post birth n= 10		
Mentum	18.1	(8 to 28)	[5.9]	11.2	(-1 to 24)	[9.1]
RAoM	-18.7	(-25 to -14)	[4.3]	-20.6	(-26 to -15)	[4.0]
LAoM	-17.7	(-24 to -9)	[5.5]	-18.6	(-25 to -10)	[4.8]
C7	22.2	(14 to 27)	[3.6]	8.4	(0 to 20)	[5.9]

Table 2-17. OP, +1, 60 kPa

Reference point	Mean distance from reference point (mm) (range) [standard deviation]					
	Post inflation, pre birth n= 10			Post birth n= 10		
Mentum	14.1	(8 to 26)	[5.3]	-12.5	(-24 to -4)	[7.4]
RAoM	-22.4	(-30 to -14)	[5.9]	-31.6	(-38 to -26)	[4.1]
LAoM	-28	(-36 to -20)	[5.1]	-29.8	(-38 to -2)	[10.3]
C7	3.2	(-8 to 12)	[5.8]	-6.8	(-10 to -4)	[2.1]

Table 2-18. OP, at spines, 40 kPa

Reference point	Mean distance from reference point (mm) (range) [standard deviation]					
	Post inflation, pre birth n= 10			Post birth n= 10		
Mentum	27.7	(20 to 35)	[4.7]	16.3	(-4 to 36)	[16.8]
RAoM	-10.1	(-18 to 3)	[5.3]	-18.5	(-30 to 0)	[10.5]
LAoM	-14.1	(-22 to -4)	[5.8]	-18.4	(-30 to -3)	[9.8]
C7	25.8	(20 to 36)	[4.8]	5.4	(-4 to 26)	[9.4]

Table 2-19. OP, at spines, 60 kPa

Reference point	Mean distance from reference point (mm) (range) [standard deviation]					
	Post inflation, pre birth n= 10			Post birth n= 10		
Mentum	22	(12 to 38)	[8.2]	-1.3	(-15 to 40)	[19.9]
RAoM	-20.7	(-26 to -15)	[3.6]	-33.3	(-40 to -18)	[6.8]
LAoM	-24.7	(-42 to -18)	[7]	-33.6	(-40 to -20)	[7.6]
C7	-1.8	(-4 to 2)	[2.2]	-7.7	(-12 to 0)	[3.7]

Table 2-20. OP, at spines, 80 kPa

Reference point	Mean distance from reference point (mm) (range) [standard deviation]					
	Post inflation, pre birth n= 10			Post birth n= 10		
Mentum	8	(-8 to 20)	[7.2]	-18	(-26 to -10)	[5.5]
RAoM	-30.8	(-40 to -18)	[7.6]	-32.2	(-36 to -24)	[3.5]
LAoM	-30.8	(-36 to -26)	[2.9]	-35	(-38 to -32)	[2.4]
C7	-1	(-14 to 10)	[7.8]	-11.4	(-14 to -8)	[2.1]

Table 2-21. ROT, +2, 40 kPa

Reference point	Mean distance from reference point (mm) (range) [standard deviation]					
	Post inflation, pre birth n= 9			Post birth n= 9		
Mentum	43.8	(36 to 54)	[5.1]	34.2	(-13 to 44)	[17.9]
RAoM	-2.2	(-14 to 18)	[11.0]	-6.4	(-42 to 5)	[13.6]
LAoM	-6	(-22 to 6)	[9.2]	-11.6	(-40 to 0)	[11.9]
C7	13.5	(6 to 22)	[4.8]	6.1	(-4 to 10)	[4.3]

During this series of births there was one instance of the cuff being applied too high on the model head, causing the cuff to slide off the head during inflation.

Table 2-22. ROT, +1, 40 kPa

Reference point	Mean distance from reference point (mm) (range) [standard deviation]					
	Post inflation, pre birth n= 10			Post birth n= 9		
Mentum	47.5	(42 to 54)	[3.0]	44.6	(38 to 48)	[3.2]
RAoM	-7.4	(-16 to 8)	[7.9]	-11.7	(-18 to -6)	[3.5]
LAoM	-8	(-18 to 4)	[10.0]	-9.7	(-18 to 16)	[10.1]
C7	12.3	(5 to 26)	[5.9]	8	(4 to 16)	[4.0]

Table 2-23. ROT, +1, 60 kPa

Reference point	Mean distance from reference point (mm) (range) [standard deviation]					
	Post inflation, pre birth n= 10			Post birth n= 10		
Mentum	37.8	(10 to 48)	[12.7]	34.8	(-28 to 46)	[22.2]
RAoM	-23.2	(-40 to -18)	[8.5]	-26.8	(-44 to -16)	[7.7]
LAoM	-23.6	(-36 to -12)	[7.5]	26.6	(-46 to -14)	[9.7]
C7	5.4	(-2 to 14)	[4.6]	7.6	(-6 to 14)	[5.6]

During this series of births there was one instance of detachment of air tube from the cuff after inflation.

Table 2-24. ROT, at spines, 40 kPa

Reference point	Mean distance from reference point (mm) (range) [standard deviation]					
	Post inflation, pre birth n= 10			Post birth n= 9		
Mentum	48.5	(44 to 52)	[2.5]	43.3	(40 to 46)	[1.9]
RAoM	-10	(-16 to 2)	[5.1]	-10.8	(-16 to -4)	[3.3]
LAoM	-14.7	(-20 to -5)	[4.4]	-14.7	(-18 to -10)	[2.6]
C7	7.8	(2 to 14)	[3.6]	9.6	(3 to 12)	[3.0]

During this series of births there was one instance of detachment of air tube from the cuff after inflation.

Table 2-25. ROT, at spines, 60 kPa

Reference point	Mean distance from reference point (mm) (range) [standard deviation]					
	Post inflation, pre birth n= 10			Post birth n= 10		
Mentum	42.8	(38 to 48)	[3.2]	41.2	(40 to 46)	[1.9]
RAoM	-19.2	(-28 to -14)	[3.8]	-25.6	(-30 to -16)	[3.7]
LAoM	-19.8	(-38 to -20)	[15.2]	-25	(-30 to -18)	[3.8]
C7	-1.8	(-10 to 4)	[4.8]	6.4	(2 to 10)	[2.6]

Table 2-26. ROT, at spines, 80 kPa

Reference point	Mean distance from reference point (mm) (range) [standard deviation]					
	Post inflation, pre birth n= 10			Post birth n= 10		
Mentum	34.2	(-8 to 46)	[15.9]	26.6	(-34 to 44)	[30.4]
RAoM	-24.2	(-42 to -18)	[7.5]	-29	(-50 to -14)	[12]
LAoM	-26.6	(-40 to -18)	[6.9]	-27.3	(-55 to -16)	[11.7]
C7	-1.2	(-8 to 8)	[4.6]	-6.8	(-20 to 10)	[7.9]

Table 2-27. ROT, +2, 60 kPa

Reference point	Mean distance from reference point (mm) (range) [standard deviation]					
	Post inflation, pre birth n= 10			Post birth n= 10		
Mentum	44	(42 to 46)	[1.6]	44.1	(42 to 48)	[1.9]
RAoM	-13	(-20 to 12)	[9.2]	-15.2	(-18 to -12)	[1.9]
LAoM	-19	(-28 to -10)	[5.2]	-17.6	(-22 to -14)	[2.8]
C7	6.4	(0 to 10)	[3.1]	8.4	(2 to 14)	[3.5]

Table 2-28. ROT, +2, 80 kPa

Reference point	Mean distance from reference point (mm) (range) [standard deviation]					
	Post inflation, pre birth n= 10			Post birth n= 10		
Mentum	45.7	(44 to 50)	[2.4]	45.7	(42 to 50)	[2.4]
RAoM	-14.7	(-22 to 0)	[6.8]	-18	(-22 to -10)	[3.6]
LAoM	-19	(-24 to -14)	[3.2]	-19.7	(-22 to -18)	[1.2]
C7	2.2	(0 to 4)	[1.6]	4.5	(2 to 10)	[2.4]

During this series of births there was one instance of detachment of air tube from the cuff after inflation.

Table 2-29. FMA, +2, 40 kPa

Reference point	Mean distance from reference point (mm) (range) [standard deviation]					
	Post inflation, pre birth n= 10			Post birth n= 7		
Posterior fontanelle	18.2	(10 to 30)	[6.4]	15.2	(9 to 24)	[4.8]
Right pinna	-12.5	(-23 to 4)	[9.2]	-15.1	(-22 to -2)	[7.4]
Left pinna	-13.8	(-23 to 12)	[10.4]	-13.8	(-23 to -2)	[8.6]
Superior sternal border	32.1	(14 to 68)	[14.8]	22.1	(13 to 38)	[9.5]

During this series of births the cuff slid off the model fetal face after inflation on three occasions.

Table 2-30. FMA, +2, 60 kPa

Reference point	Mean distance from reference point (mm) (range) [standard deviation]					
	Post inflation, pre birth n= 10			Post birth n= 10		
Posterior fontanelle	-85	(-92 to -78)	[36.1]	-76	(-80 to -68)	[27.2]
Right pinna	-9.5	(-18 to 0)	[6]	-31.7	(-36 to -24)	[4.1]
Left pinna	-11.2	(-20 to -4)	[5.4]	-33.4	(-40 to -26)	[4.3]
Superior sternal border	92.3	(82 to 110)	[8.4]	81.2	(68 to 92)	[9.7]

During this series of births the cuff slid off the model fetal face after inflation on three occasions.

When performed on a FMA presentation, +2 spines and using an 80 kPa inflation pressure, the cuff slid off the model fetal face on eight occasions – therefore no results are presented for this attempt.

2.9 Results of simulations with caput head

Table 2-31. Caput head, OA, +2, 40 kPa

Reference point	Mean distance from reference point (mm) (range) [standard deviation]					
	Post inflation, pre birth n= 10			Post birth n= 10		
Mentum	45.9	(40 to 52)	[4.3]	41.4	(36 to 48)	[3.7]
RAoM	-10.7	(-16 to -6)	[3.4]	-13	(-16 to -10)	[2.3]
LAoM	-15.9	(-70 to -8)	[19.3]	-11.4	(-16 to -8)	[2.3]
C7	10.6	(4 to 17)	[3.3]	11.9	(6 to 17)	[3.5]

Table 2-32. Caput head, OA, +2, 60 kPa

Reference point	Mean distance from reference point (mm) (range) [standard deviation]					
	Post inflation, pre birth n= 10			Post birth n= 10		
Mentum	46.6	(40 to 50)	[3.1]	43.1	(40 to 46)	[2.2]
RAoM	-15.8	(-12 to -10)	[2.7]	-21.4	(-24 to -18)	[2.5]
LAoM	-16.6	(-18 to -14)	[1.9]	-22.1	(-25 to -18)	[2.9]
C7	16.3	(14 to 21)	[2.5]	9	(7 to 10)	[1.2]

Table 2-33. Caput head, OA, +2, 80 kPa

Reference point	Mean distance from reference point (mm) (range) [standard deviation]					
	Post inflation, pre birth n= 10			Post birth n= 10		
Mentum	47	(42 to 52)	[3.1]	45.7	(42 to 48)	[1.8]
RAoM	-14.4	(-18 to -10)	[2.5]	-19.1	(-25 to -17)	[2.4]
LAoM	-14	(-20 to -6)	[4.2]	-16	(-14 to -18)	[1.6]
C7	9.5	(6 to 14)	[2.9]	6.5	(4 to 13)	[3.2]

Table 2-34. Caput head, OA, at spines, 40 kPa

Reference point	Mean distance from reference point (mm) (range) [standard deviation]					
	Post inflation, pre birth n= 10			Post birth n= 10		
Mentum	42.6	(34 to 50)	[5.1]	41	(38 to 50)	[3.7]
RAoM	-16.7	(-20 to -14)	[2.0]	-16.2	(-18 to -14)	[1.4]
LAoM	-18.2	(-24 to -15)	[2.7]	-17.1	(-20 to -15)	[2.4]
C7	17.5	(7 to 24)	[4.8]	14.5	(10 to 20)	[2.9]

Table 2-35. Caput head, OA, at spines, 60 kPa

Reference point	Mean distance from reference point (mm) (range) [standard deviation]					
	Post inflation, pre birth n= 10			Post birth n= 10		
Mentum	45.8	(44 to 48)	[1.5]	40.7	(35 to 44)	[2.4]
RAoM	-15.5	(-20 to -12)	[2.6]	-21.8	(-28 to -16)	[3.7]
LAoM	-16.5	(-14 to -24)	[3.2]	-23.1	(-26 to -16)	[3.3]
C7	19.6	(14 to 24)	[3.8]	9.9	(8 to 12)	[1.5]

Table 2-36. Caput head, OA, at spines, 80 kPa

Reference point	Mean distance from reference point (mm) (range) [standard deviation]					
	Post inflation, pre birth n= 10			Post birth n= 10		
Mentum	45.2	(40 to 48)	[2.5]	43.2	(40 to 46)	[2.5]
RAoM	-20.9	(-24 to -15)	[2.9	-29.7	(-33 to -24)	[3.3]
LAoM	-23.1	(-28 to -18)	[3.8]	-31.7	(-35 to -25)	[3.9]
C7	12.6	(10 to 16)	[1.8]	6.6	(6 to 9)	[1.0]

Table 2-37. Caput head, OP, +2, 40 kPa

Reference point	Mean distance from reference point (mm) (range) [standard deviation]					
	Post inflation, pre birth n= 10			Post birth n= 10		
Mentum	37	(26 to 46)	[5.8]	30.6	(-10 to 45)	[15.6]
RAoM	-7	(-14 to -2)	[3.6]	-13.7	(-34 to -8)	[7.7]
LAoM	-8.4	(-16 to -4)	[3.9]	-12.8	(-20 to -6)	[4.5]
C7	40.1	(32 to 46)	[4.0]	17.4	(10 to 28)	[5.7]

Table 2-38. Caput head, ROT, +2, 40 kPa

Reference point	Mean distance from reference point (mm) (range) [standard deviation]					
	Post inflation, pre birth n= 10			Post birth n= 10		
Mentum	48	(44 to 50)	[3.4]	43.5	(40 to 46)	[2.4]
RAoM	-9.6	(-16 to 0)	[4.5]	-10.5	(-15 to -6)	[3.4]
LAoM	-10	(-16 to -6)	[3.5]	-11.4	(-18 to -4)	[3.5]
C7	21.9	(10 to 30)	[5.7]	19.4	(16 to 24)	[2.8]

2.10 Results of simulations with small head

Table 2-39. Small head, OA, +2, 40 kPa

Reference point	Mean distance from reference point (mm) (range) [standard deviation]					
	Post inflation, pre birth n= 10			Post birth n= 10		
Mentum	35.3	(22 to 42)	[5.7]	28.1	(-27 to 40)	[23.6]
RAoM	-21	(-25 to -14)	[3.3]	-18.9	(-30 to -9)	[6.8]
LAoM	-20.8	(-42 to -12)	[8.1]	-17.5	(-34 to -8)	[8.7]
C7	8.1	(-1 to 12)	[3.8]	10.1	(0 to 18)	[5.9]

Table 2-40. Small head, OA, +2, 60 kPa

Reference point	Mean distance from reference point (mm) (range) [standard deviation]					
	Post inflation, pre birth n= 10			Post birth n= 9		
Mentum	6.6	(-4 to 26)	[9.0]	-11.6	(-28 to 40)	[19.8]
RAoM	-34.8	(-40 to -26)	[4.1]	-36	(-46 to -22)	[6.4]
LAoM	-37.7	(-44 to -13)	[9.2]	-38.4	(-46 to -18)	[8.0]
C7	5.1	(2 to 14)	[3.4]	2.4	(-2 to 18)	[6.1]

During this series of births there was once instance of bag failure during traction

Table 2-41. Small head, OA, +2, 80 kPa

Reference point	Mean distance from reference point (mm) (range) [standard deviation]					
	Post inflation, pre birth n= 10			Post birth n= 10		
Mentum	17	(0 to 30)	[11.3]	-19	(-32 to -10)	[9.0]
RAoM	-26.6	(-30 to -22)	[3.4]	-30.4	(-34 to -24)	[3.5]
LAoM	-26.4	(-36 to -20)	[5.4]	-30.2	(-34 to -24)	[3.2]
C7	3.6	(0 to 8)	[2.5]	5	(-2 to 14)	[5.5]

Table 2-42. Small head, OA, +1, 40 kPa

Reference point	Mean distance from reference point (mm) (range) [standard deviation]					
	Post inflation, pre birth n= 10			Post birth n= 10		
Mentum	26.8	(20 to 38)	[4.1]	6.1	(-20 to 40)	[26.9]
RAoM	-28.2	(-36 to -24)	[4.2]	-27.4	(-35 to -19)	[5.8]
LAoM	-24	(-30 to 0)	[9.2]	-28.1	(-40 to -18)	[7.5]
C7	6.2	(3 to 8)	[1.8]	7.7	(-2 to 16)	[6.2]

Table 2-43. Small head, OA, at spines, 40 kPa

Reference point	Mean distance from reference point (mm) (range) [standard deviation]					
	Post inflation, pre birth n= 10			Post birth n= 10		
Mentum	35.9	(22 to 44)	[7.2]	35	(4 to 42)	[11.3]
RAoM	-20.5	(-26 to -15)	[3.7]	-14.7	(-24 to -4)	[5.8]
LAoM	-21	(-15 to -24)	[3.7]	-15	(-30 to -5)	[6.6]
C7	10.6	(0 to 24)	[7.0]	14.8	(2 to 25)	[6.2]

Table 2-44. Small head, OA, at spines, 60 kPa

Reference point	Mean distance from reference point (mm) (range) [standard deviation]					
	Post inflation, pre birth n= 10			Post birth n= 10		
Mentum	2.4	(-10 to 35)	[12.2]	-13.8	(-20 to -15)	[12.0]
RAoM	-37.1	(-44 to -30)	[4.3]	-40.3	(-45 to -36)	[2.9]
LAoM	-37.4	(-42 to -34)	[5.3]	-39.2	(-42 to -34)	[2.7]
C7	3.2	(-2 to 10)	[4.1]	0.2	(-2 to 2)	[1.8]

Table 2-45. Small head, OA, at spines, 80 kPa

Reference point	Mean distance from reference point (mm) (range) [standard deviation]					
	Post inflation, pre birth n= 10			Post birth n= 10		
Mentum	3	(-2 to 6)	[2.5]	-17.7	(-24 to -14)	[3.3]
RAoM	-39.8	(-46 to -38)	[2.4]	-39.6	(-44 to -36)	[2.5]
LAoM	-41	(-48 to -38)	[3.0]	-38.8	(-42 to -35)	[1.9]
C7	4.6	(0 to 14)	[3.7]	2.6	(0 to 4)	[1.6]

Table 2-46. Small head, OP, +2, 40 kPa

Reference point	Mean distance from reference point (mm) (range) [standard deviation]					
	Post inflation, pre birth n= 10			Post birth n= 10		
Mentum	9.6	(-4 to 20)	[7.3]	-20.7	(-35 to 0)	[10.3]
RAoM	-24.2	(-54 to -10)	[14.3]	-27.4	(-40 to -20)	[5.9]
LAoM	-27	(-54 to -14)	[11.8]	-29.4	(-40 to -22)	[5.7]
C7	19.2	(-20 to 30)	[14.8]	2.2	(-2 to 12)	[4.8]

Table 2-47. Small head, OP, +1, 40 kPa

Reference point	Mean distance from reference point (mm) (range) [standard deviation]					
	Post inflation, pre birth n= 10			Post birth n= 10		
Mentum	8.8	(-2 to 30)	[9.8]	-12.7	(-32 to 36)	[26.1]
RAoM	-25	(-42 to -12)	[11.4]	-31.4	(-45 to -18)	[8.1]
LAoM	-25.4	(-36 to -18)	[6.1]	-27.9	(-38 to -9)	[8.5]
C7	12.4	(2 to 28)	[9.3]	0.4	(-6 to 8)	[4.0]

Table 2-48. Small head, OP, at spines, 40 kPa

Reference point	Mean distance from reference point (mm) (range) [standard deviation]					
	Post inflation, pre birth n= 10			Post birth n= 10		
Mentum	10.7	(0 to 28)	[8.0]	-22.4	(-36 to 36)	[21.0]
RAoM	-26.4	(-34 to -18)	[6.1]	-34.2	(-40 to -18)	[6.4]
LAoM	-28.8	(-44 to -20)	[8.1]	-30.8	(-36 to -14)	[6.5]
C7	13.6	(0 to 24)	[8.5]	1.7	(-4 to 10)	[5.2]

Table 2-49. Small head, ROT, +2, 40 kPa

Reference point	Mean distance from reference point (mm) (range) [standard deviation]					
	Post inflation, pre birth n= 10			Post birth n= 10		
Mentum	35.9	(20 to 44)	[7.4]	40.2	(36 to 44)	[2.0]
RAoM	-21.5	(-25 to -18)	[2.5]	-13.4	(-18 to -10)	[2.3]
LAoM	-25	(-30 to -20)	[3.8]	-10.6	(-13 to -8)	[1.7]
C7	11.7	(2 to 18)	[4.3]	17.5	(-10 to 25)	[10.2]

Table 2-50. Small head, ROT, +1, 40 kPa

Reference point	Mean distance from reference point (mm) (range) [standard deviation]					
	Post inflation, pre birth n= 10			Post birth n= 10		
Mentum	37	(20 to 40)	[6.3]	29.8	(-30 to 40)	[21.8]
RAoM	-29.6	(-36 to -20)	[5.3]	-17.5	(-46 to -10)	[10.4]
LAoM	-33.7	(-40 to -22)	[6.0]	-17	(-36 to -10)	[7.3]
C7	6	(2 to 10)	[3.1]	20.9	(2 to 26)	[7.1]

Table 2-51. Small head, ROT, at spines, 40 kPa

Reference point	Mean distance from reference point (mm) (range) [standard deviation]					
	Post inflation, pre birth n= 10			Post birth n= 10		
Mentum	35.2	(24 to 42)	[5.8]	37	(34 to 40)	[1.9]
RAoM	-26	(-35 to -15)	[5.2]	-14.2	(-16 to -12)	[1.5]
LAoM	-25.9	(-34 to -18)	[5.7]	-14.2	(-16 to -10)	[1.7]
C7	16.7	(6 to 32)	[6.6]	26.4	(22 to 30)	[2.5]

Chapter 3 Perineal distension associated with the use of forceps, Kiwi ventouse and BD Odon Device

3.1 Abstract

Objective

To investigate the perineal distention during simulated operative vaginal births conducted with forceps, Kiwi and the BD Odon Device

Design

Observational simulation study

Setting

North Bristol NHS Trust, UK

Population or Sample

40 simulated operative vaginal births

Methods

A PROMPT Flex maternal/fetal mannequin was used. Perineal distension was determined by recording maximum perineal distention during a simulated operative vaginal birth in a scenario employing an inappropriately non-deflated air cuff and an appropriately deflated air cuff (for the BD Odon Device), the Kiwi ventouse and non-rotational forceps.

Main Outcome Measures

Maximal perineal distension during birth.

Results

The BD Odon Device was not associated with more perineal distension than forceps or Kiwi ventouse (21mm vs 26mm vs 21mm respectively at posterior fourchette) when deflated correctly.

Conclusions

The BD Odon Device generates similar levels of perineal distension compared to Kiwi ventouse when used correctly.

Chapter 3 - Perineal distension associated with the use of forceps, Kiwi ventouse and BD Odon Device

3.2 Introduction

Operative vaginal birth, while a beneficial intervention for both mother and baby in well-trained hands (6), is associated with adverse maternal and neonatal outcomes. Specifically, OVB is associated with a greater degree of maternal perineal trauma than unassisted vaginal birth (117,118).

Maternal perineal trauma causes both short and long-term problems for women – in the short term, women can sustain obstetric anal sphincter injuries (OASI), and feacal incontinence (FI), anal incontinence (AI), urinary incontinence (UI) and pelvic organ prolapse (POP) in the medium or long term.

These outcomes have significant impacts on maternal quality of life and future reproductive career. Taken together, women sustaining some degree of perineal trauma are more likely to report bothersome symptoms of UI, AI, FI or POP from one year after birth (119) to 20 years after birth (120,121). Moreover, women who sustained an OASI, compared to women who had a vaginal birth without OASI, are specifically more likely to report higher rates of FI and AI (122), poorer sexual function (123), as well as poorer overall quality of life (124) overall.

In view of these common, severe adverse events, the development of any new device for OVB should consider how best to predict and reduce these outcomes. Given the short time-span of any outcome data gathering, and the need to clearly classify any reported outcomes, it is reasonable that this effort focuses primarily on predicting and reducing the risk of OASI, both as a negative outcome in itself and as a predictor of longer term negative outcomes.

The BD Odon Device consists of an inflatable circular air cuff attached to a thin circumferential polyethylene sleeve. A semi-rigid plastic applicator is used to place the air cuff and sleeve into the birth canal, past the widest diameter of the fetal head. The air cuff is inflated around the fetal head, and the applicator is removed. During maternal contractions the accoucheur applies traction to the polyethylene sleeve, to assist birth of the baby.

The air cuff provides the traction anchor point of the BD Odon Device, and is the part of the device most likely to contribute to severe maternal trauma – however, the expected rate of this trauma/OASI is unknown, and there are no tools currently in existence that allow for a reasoned estimate to be made.

3.2.1 Predicting OASI

Multiple risk factors for OASI have been identified, such as advancing maternal age (129,130), nulliparity (122,131,132), high birthweight (>4000g) (122,129,132), ethnicity (women of Asian origin are more at risk of OASI than Caucasian women) (129,133,134), greater fetal head circumference (135,136), and persistent OP position (55,125,126).
In addition, OVB has been clearly identified as a predictive of increased risk of sustaining an OASI by individual studies (122,129,132), systematic reviews (127,128) and professional body guidance (12,129).
Within this, there are marked differences in the rate of OASI between forceps and ventouse, with the most recent Cochrane meta-analysis reporting OASI rates for all types of pooled forceps births of 14%, compared to 7.5% for all ventouse (11). This is supported by retrospective studies of national registries in the UK and Netherlands, which have demonstrated 2 to 3-fold higher rates of OASI among women delivered with forceps versus women delivered with ventouse (86,130).

3.2.2 Mechanism of OASI

While there remains debate about the relative importance of different contributory factors, the underlying mechanism of OASI is generally agreed to be displacement of the anal sphincter past its point of maximal elastic stretch during crowning of the fetal head (127,131,132). This suggests that any clinical circumstance which widens the presenting diameter of the fetal head is likely to increase the rate of OASI, and would account for the higher rate of OASI found with increased head circumference, OP position and forceps.
While the absolute circumference of a fetal head +/- any instrument may be the proximate cause of a tear, simply measuring the circumference of any fetal head/instrument complex is not sufficient alone to predict the likelihood of a significant tear, as any clinical scenario will entail individual (and often small) variations in fetal head position and instrument placement - the risk of tearing will not be identical from one clinical scenario to the next.
Therefore, any attempt to quantify the risk of tearing between instruments should take

these variations in placement and fetal head position into account – this may be best done by measuring the effect that any particular fetal head and instrument position has on the maternal tissues themselves, rather than simply the dimensions of the head and instrument together.

It has already been established that the degree of stretch that can be accommodated by maternal tissues has a predictive value for a significant tear. Women whose perineums are either unable to stretch sufficiently or which stretch significantly more than average are more likely to sustain a significant tear - Lai et al. found that nulliparous women who stretched less had a higher chance of sustaining a significant tear (percentage of perineal stretch from baseline in group with 1st degree tear versus those with 2nd degree tear = 30.9% vs 20.2%, p=0.02) (133), while Walfisch et al. found that excessive stretching (women whose perineum stretched more than 150% from resting were significantly more likely to require suturing (OR 2.11, p<0.01)) (134).

Therefore, while it is generally agreed that a greater presenting part circumference at crowning results in a higher likelihood of significant perineal trauma, the potential displacement effect of such a presenting part on maternal tissues may be a more sensitive predictor of the likelihood of perineal trauma.

3.2.3 Quantifying the risk of OASI in simulation

At present there are no validated simulation tools to assess the likelihood of perineal trauma during birth. Given the predictive role of potential displacement of maternal tissues in perineal trauma, we chose to develop a tool for measuring perineal displacement at crowning, as a pragmatic means of estimating likelihood of trauma. We sought to determine the perineal distension during simulated births with the BD Odon Device, using an appropriately deflated cuff, non-rotational forceps and Kiwi ventouse. Misuse of the BD Odon Device, where the air cuff remains inflated during crowning contrary to Instructions For Use, was also simulated using a modified procedure, to evaluate the degree of perineal distention provided by the inflated air cuff if the practitioner inadvertently failed to deflate the air cuff prior to crowning of the fetal head.

3.3 Methods

3.3.1 Simulation of operative vaginal births

The PROMPT birthing simulator fetal mannequin was used. This mannequin has, an average size head for a term fetus with a bi-parietal diameter (BPD) of 96mm, comparable to the 50th centile of 97mm at 39 to 40 weeks gestation (12) (Figure 3-1).

Figure 3-1. Model fetal head with BPD of 96mm

All simulated OVBs were conducted by a single operator (SO'B).

Forty simulated OVBs were performed to investigate the placement of the BD Odon Device. The 50th centile head diameter fetal mannequin was used to measure the perineal distension during birth in four separate clinical scenarios (10 births per scenario):

(i) BD Odon Device, OA position, vertex 2cm below the ischial spines (station +2cm), air cuff inflation pressure of 40kPa, cuff appropriately deflated at crowning of the fetal head

(ii) BD Odon Device, OA position, vertex 2cm below the ischial spines (station +2cm), air cuff inflation pressure of 40kPa, cuff inappropriately not deflated at crowning of the fetal head

(iii) Kiwi ventouse, OA position, station +2cm

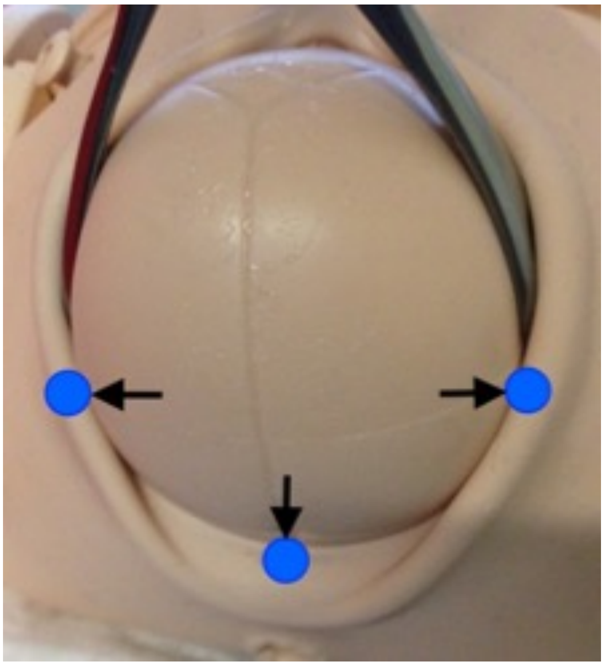
(iv) Non-rotational forceps, OA position, station +2cm

Perineal distension with the vertex at 2 cm below the ischial spines (the baseline) was measured for each simulation prior to the application of an instrument (BD Odon Device, Kiwi or non-rotational forceps). Measurements were taken from three fixed points on the maternal mannequin; (i) posterior fourchette (PF), (ii) left mid-vestibular edge (LMVE) and (iii) right mid-vestibular edge (RMVE) (Figure 3-2).

Figure 3-2. Perineal displacement measurement points

Measurements were repeated at the point of maximum perineal distension (either laterally for LMVE and RMVE or directly inferiorly for PF) during the simulated birth (Figure 3-3).

Figure 3-3. Maximal perineal distention



The difference between the baseline and maximum distension measurements of each reference point (LMVE, RMVE, PF) in mm were calculated to determine the maximum perineal distension in each of the four scenarios described above. The scenario where the BD Odon Device cuff was left intentionally inflated during crowning (contrary to instructions for use) was included to simulate a worst-case scenario where the operator neglects to deflate the cuff.

Data from the posterior fourchette were analysed as a single outcome, while data from LMVE and RMVEs were pooled to give a composite measure of lateral perineal distension. Results are presented using descriptive statistics for distention data in each scenario. As data was not used for inferential comparisons it has not been transformed into a normal distribution. Therefore, the mean and range is given for all data.

3.4 Results

Data are presented as means with ranges, as they were normally distributed (assessed using simultaneously Kurtosis statistics and the coefficient of skewness of the variable distribution as well as the qq plot and pp plot of this distribution).

3.4.1 Perineal distension

During birth, when used correctly, there was no difference between the means of posterior fourchette distension using the BD Odon Device and Kiwi ventouse. When the BD Odon Device was used with the air cuff purposefully left inflated at crowning (simulating a user error) to investigate perineal distension in a worst-case scenario, greater perineal distension was observed at the posterior fourchette than with obstetric forceps or Kiwi ventouse (Table 3-1).

Table 3-1. Perineal distension associated with the use of BD Odon Device, non-rotational forceps and Kiwi in OA, 2cm below the ischial spines

Instrument	BD Odon Device (cuff correctly deflated prior to crowning) n = 10	BD Odon Device (cuff incorrectly inflated to 40kPa during crowning) n=10	Kiwi n=10	Forceps n=10
Mean maximal perineal distension at the posterior fourchette during birth (mm) (range)	21 (13 to 33)	36 (28 to 42)	21 (18 to 24)	26 (18 to 28)
Mean maximal lateral perineal distension during birth (mm) (range)	18 (11 to 28)	27 (14 to 34)	19 (7 to 25)	25 (16 to 31)

3.5 Discussion

3.5.1 Main Findings

When correctly used, the BD Odon Device did not generate greater perineal distention than Kiwi ventouse or forceps. However, in 'worst case' simulations in which the air cuff was not deflated, the BD Odon Device generated greater distention at the posterior fourchette than either forceps or Kiwi. These findings suggest that incorrect use of the BD Odon Device, by not deflating the air cuff prior to crowning, may generate similar or higher rates of perineal tears than forceps, whereas correct use of the BD Odon Device produced similar perineal distention to the Kiwi. This finding highlights the importance of training accoucheurs to use the BD Odon Device correctly.

3.5.2 Strengths and Limitations

This is the first study to prospectively investigate the performance of a novel device for operative vaginal birth using simulation.

All simulations were performed by a single operator, which assisted internal consistency of measurement and eliminated inter-operator variability. However, we recognise the inherent limitations of this strategy, in particular the possibility of repeated systematic error.

No assessment was made of the behaviour of any instrument with the model fetal head in an OP position. While perineal distention is likely to be greater that that generated in an OA position, our lack of quantification is a limitation of the study.

A further potential criticism of this study is the uncertainty whether the findings are generalisable to actual use of any device in clinical practice. We also acknowledge that there are no anatomical measurements with sufficient predictive validity to accurately assess the risk of perineal tears. However, our comparison of perineal distension during Kiwi ventouse, forceps and the BD Odon Device is a pragmatic proxy for prediction of perineal tears. We also believe that while the chosen methodology may not be externally valid and able to predict the absolute rates of tears experienced in vivo, the findings should be internally consistent – i.e. the rate of OASI is likely to be similar between deflated BD Odon Device and Kiwi ventouse, and less than forceps.

3.5.3 Interpretation (in light of other evidence)

A wider presenting part is more likely to cause maternal trauma during birth (62,129,133-137). Simulated perineal displacement may be a usable direct measurement that will predict the expected rate of perineal trauma during birth.

3.6 Conclusions

In 40 simulations, using a robust and validated anatomical model, the perineal distension associated with the use of the BD Odon Device was similar to the Kiwi ventouse when the air cuff was deflated appropriately just prior to birth of the fetal head, and greater than forceps when the cuff was not deflated. These findings should be correlated with outcomes form a clinical trial, which will either validate or reject our methodological model.

Chapter 4 Traction over a model fetal head and neck associated with the use of forceps, Kiwi ventouse and the BD Odon Device

4.1 Abstract

Objective

To determine the pressure and traction forces exerted on a model fetal head by the BD Odon Device, forceps and Kiwi ventouse during simulated births.

Design

Simulation study.

Setting

Simulated operative vaginal birth.

Population or Sample

20 simulated operative vaginal births.

Methods

A bespoke fetal mannequin with a strain gauge across the neck was used to investigate traction across the neck during 20 simulated births using the BD Odon Device, non-rotational forceps and Kiwi ventouse.

Main Outcome Measures

Peak traction force generated until instrument failure using the BD Odon Device, forceps and Kiwi ventouse.

Results

In cases of true cephalic disproportion the BD Odon Device 'popped-off' at a lower traction force than forceps (208N vs 270N).

Conclusions

In cases in which delivery of the fetal head is not possible due to cephalo-pelvic disproportion, lower traction forces could be applied using the BD Odon Device than with forceps before the procedure was abandoned due to device failure.

4.2 Introduction

Some complications of OVB are related to the traction force required to complete the birth. Specifically, trauma is more likely to occur if greater levels of traction are transmitted to the baby during application and traction. This has been shown in the case of both forceps and ventouse.

In the case of forceps, there is a well-demonstrated relationship between the number of pulls and adverse neonatal outcomes – as direct levels of traction have never been measured (such as with the use of a Newton meter or other device), the number of pulls serves as a pragmatic proxy for the overall amount of traction force transmitted to the baby by the accoucheur via the instrument. Murphy et al. reported significantly increased rates of adverse neonatal outcomes following more than three pulls (6), while Matsumo et al. demonstrated a statistically significant increased risk of neonatal facial injury after three pulls relative to one pull (OR 16, CIs 2.1 to 123.3, $p < 0.01$) (72). This recognition of the causal link between number of pulls and neonatal adverse outcomes has been widely recognised within the profession – limiting the number of pulls to three has been adopted by the RCOG and is clearly stated in both the RCOG OVB Green-top guideline and the RCOG official OVB training guide (ROBuST Manual) (13,40). Guidelines form other national professional bodies (American College of Obstetricians & Gynecologists, Canadian Society of Obstetricians and Gynecologists, Royal Australian and New Zealand College of Obstetricians and Gynaecologists and Collège National des Gynécologues et Obstétriciens Français) have also recommended a limited number of pulls, but have not specified an exact number (135-138).

In the case of ventouse, although the absolute level of traction that can be transmitted is lower than with those of forceps, the association between traction and adverse outcomes has again been demonstrated. Vacca et al. showed that deliveries completed with a traction force that never exceeded 115 N versus those that did, were less likely to be associated with both neonatal scalp abrasion (RR 0.38, CI 0.12 to 1.24) and cephalohaematoma (RR 0.34, CI 0.08 to 1.41), although neither of these were deemed to be statistically significant (71).

In addition to studies looking directly at the amount of traction applied (including via the proxy of the number of pulls) and adverse maternal and neonatal outcomes, there is further supporting evidence from studies which have stratified attempted OVBs by indication. In their retrospective cohort study of all attempted mid-pelvic OVBs within British Columbia between 2004 and 2014, Muraca et al. found that OVBs performed for the indication of 'dystocia' were more likely to be associated with severe maternal and neonatal morbidity than those performed for 'fetal distress' alone (dystocia vs fetal distress respectively - severe maternal morbidity: forceps RR 1.57 vs 2.34, ventouse RR 2.29 vs RR 0.79, severe neonatal morbidity: forceps RR 2.11 vs 1.15, ventouse RR 2.17 vs 1.28) (57). While it is not documented that practitioners used more force or a greater number of pulls to expedite the births conducted for dystocia, it is likely that greater traction was used in these births overall.

While this evidence for the association between the rate of adverse outcomes and traction force applied is intuitive, it does not take into account the risk of failure, itself a major source of morbidity for both mothers and their babies. Failure to achieve birth is likely to have some association with the ability to correctly apply traction to the baby, and an inability to apply a sufficient amount of traction is likely to be responsible for at least some failures to achieve a vaginal delivery. This is supported by the general superiority of forceps over ventouse at achieving vaginal delivery (11) (as forceps are able to apply more traction than ventouse), as well as a small study showing that ventouse cups that are able to apply more traction to the fetal head have lower failure rates. Hofmeyer et al., in a small, unblinded RCT of 31 women showed that the rate of failure during the use of rigid mushroom cups (Bird's and O'Neil), which were able to generate significantly higher levels of maximum traction force than soft cups (Silc and Silastic) (158 N vs 110 N), was significantly lower than that found during the use of soft cups (OR 12.9, CIs 12.2 to 138). While it is desirable to prevent accoucheurs from applying an excessive amount of traction which could result in harm, this should not come at the expense of being able to apply the amount of traction required to achieve birth if used correctly – this could be established by measuring the pop-off point. The pop-off point is the point at which the addition of additional traction force results in the instrument either coming off the fetal head (as in ventouse) or being deformed so that it is unable to apply further traction (forceps). As the pop-off point represents the juncture at which no further traction force can be applied, it should act as a useful marker for the potential adverse outcomes that would be associated with that particular point – if the pop-off point is low, the instrument is unlikely to cause harm due to excessive traction, but may fail more than is acceptable, whereas if it is too high, the instrument may rarely fail but could be associated with unacceptably high levels of trauma in unskilled hands.

The BD Odon Device consists of an inflatable circular air cuff attached to a thin circumferential polyethylene sleeve. A plastic applicator places the air cuff and sleeve into the birth canal, past the widest diameter of the fetal head. The air cuff is inflated, and the applicator removed. During maternal contractions the accoucheur applies traction to the sleeve, to expedite the birth.

The use of an air cuff positioned circumferentially around the fetal head acts as the 'anchor point' for traction, compared to the zygomatic arches in the case of forceps or the cup position in the case of ventouse.

We sought to determine the pop-off point for currently used instruments as well as the BD Odon Device in order to determine the likely potential for both failure and harm in clinical practice due to under or over-application of traction.

We developed a simulation model to study the force applied across the fetal head and neck during attempted OVB in a situation of true cephalo-pelvic disproportion where the head is not deliverable vaginally. The model head was used to compare forces on the fetal head in births using (i) non-rotational forceps, (ii) Kiwi ventouse and (iii) the BD Odon Device.

4.3 Simulation of operative vaginal births

A PROMPT Flex Force Monitoring fetal mannequin was used with a standard PROMPT Flex® maternal mannequin and associated software to enable the simulation of operative vaginal births.

A series of simulated OVBs using the BD Odon Device, Kiwi ventouse and non-rotational forceps were performed by a single operator (SO'B). The air cuff of the BD Odon Device was inflated to 60kPa and 80kPa. This is the expected pressure range that will be used in-vivo. Twenty scenarios were performed to evaluate the force at which a device would detach or 'pop-off' the fetal head when the head was not deliverable. A bespoke 'pelvic shelf' was produced to prevent decent and birth of the fetus in order to simulate cephalo-pelvic disproportion. The pelvic shelf consisted of two steel bars inserted through non-deformable attachments at the fetal shoulders, which were then laid across the upper brim of the model pelvis. This prevented any downward movement of the model fetus. The traction force (N) exerted during attempted non-rotational forceps (n=5), kiwi ventouse (n=5) and BD Odon Device with cuff inflated to 60kPa (n = 5) and BD Odon Device with cuff inflated to 80kPa birth (n=5) on a cephalic presentation, direct OA position with the vertex at the ischial spines was measured using the integrated force monitoring device within the PROMPT Flex fetal mannequin.

Traction force data was captured by the PROMPT Flex® birthing simulator software (Limbs &Things, Bristol, UK) at 20Hz and subsequently exported for analysis. Failure was considered to have occurred when the device pop-off the fetal head. Forceps failure was diagnosed when, due to the force of traction, the forceps blades came apart such that they also slipped off the fetal head.

Results are presented using descriptive statistical data due to the limited number of repetitions within each scenario. Data are reported as mean values for each dataset with full ranges of all values.

4.4 Results

Twenty simulated operative vaginal births were performed (Table 4-1).

Table 4-1. Summary of simulations performed

Instrument	Position	Inflation pressure (kPa)	Number of births
BD Odon	OA	60	5
Device	OA	80	5
Forceps	OA		5
Kiwi ventouse	OA		5
		Total births	20

Data are presented as means with ranges, as they were normally distributed (assessed using simultaneously Kurtosis statistics and the coefficient of skewness of the variable distribution as well as the qq plot and pp plot of this distribution).

4.4.1 Evaluation of the force at which a device detaches from the model fetal head when the head is not deliverable

The maximum traction force applied before the device disengaged from the fetal head during an obstructed OVB (in which it was not possible for the fetal head to be delivered) was greater in non-rotational forceps (270N) compared to attempts using the BD Odon Device at 80kPa inflation pressure (208N), 60kPa inflation pressure (167N) and Kiwi ventouse (70N) (Table 4-2). At disengagement, the BD Odon Device and Kiwi ventouse 'popped-off' the fetal head. At disengagement point, the traction on the forceps was sufficient to force the blades apart around the fetal head resulting in disengagement of the forceps. Therefore the force transmitted by forceps was limited by the material resistance of the fetal head, and not traction force applied by the operator.

Table 4-2. Traction force generated across fetal neck at pop-off of instrument

Mean pop-off force (N) [range]			
BD Odon Device, 80kPa inflation pressure n = 5	**BD Odon Device, 60kPa inflation pressure n = 5**	**Non-rotational forceps n = 5**	**Kiwi ventouse n = 5**
208 [192 to 283]	167 [159 to 183]	270 [251 to 309]	70 [129 to 145]

4.5 Discussion

4.5.1 Main Findings

When used inappropriately in an obstructed birth and used forcefully until device failure, the BD Odon Device generates substantially less traction than forceps but more than Kiwi ventouse. However, as our simulator was unable to generate a chignon, the true pop-off/failure force for a Kiwi ventouse is likely to be higher in clinical practice – previous studies have demonstrated pop-off forces of between 110N to 130N (71). This is still however lower than the traction forceps reported here for the BD Odon Device.

4.5.2 Interpretation

Greater traction forces used in OVBs correlate with higher rates of neonatal injury and maternal anal sphincter damage (71). The BD Odon Device generates less traction force before device failure than forceps. The incidence of adverse outcomes related to inappropriate traction force applied using an BD Odon Device is therefore likely to be less than those associated with forceps. Previous research has demonstrated that traction forces of 110 to 130N are routine using Kiwi (71), suggesting that rates of adverse outcomes due to high traction may be comparable between the BD Odon Device and the Kiwi ventouse. The BD Odon Device does not generate negative pressure on the fetal head, reducing the likelihood of adverse outcomes such as subgaleal or retinal haemorrhage and cephalohaematoma being associated with the use of a BD Odon Device when compared to vacuum assisted births.

If the assumption that there is a correlation between the amount of traction that can be applied and the chance of failure is correct, then we would expect the BD Odon Device to be associated with a higher level of failure than forceps, but lower than Kiwi ventouse.

4.5.3 Strengths and Limitations

We have not been able to quantify negative pressures, or replicate the chignon associated with ventouse births. However, due to its mechanism of action we are confident that the BD Odon Device does not generate any negative pressure on the fetal head and therefore will not cause a chignon. It is therefore unlikely that the most serious outcomes generated by negative pressure (such as subgaleal haemorrhage), or those associated with movement of the cup over an established chignon (scalp abrasion/avulsion) will occur following births conducted using the BD Odon Device.

4.6 Conclusion

The BD Odon Device generates lower peak pressure than non-rotational forceps during simulated birth and does not exert a negative pressure required to perform a vacuum assisted birth. It is therefore likely that the BD Odon Device will be associated with lower adverse outcomes related to both peak pressure (bruising, facial nerve palsy, skull fracture) and negative pressure (subgaleal or retinal haemorrhage and cephalohaematoma, scalp abrasion/avulsion) compared to currently available instruments (forceps and ventouse).

This study has generated sufficient data to suggest that, in this regard, the BD Odon Device is likely to be as safe, if not safer, than forceps and ventouse in clinical practice. A clinical trial of the BD Odon Device versus either forceps or ventouse would help to validate this model.

Chapter 5 Simulation of pressure on a model fetal head and neck associated with the use of forceps, Kiwi ventouse and the BD Odon Device

5.1 Abstract

Objective

To determine the pressure exerted on a model fetal head by the BD Odon Device, forceps and Kiwi ventouse during simulated births.

Design

Simulation study.

Setting

Simulated operative vaginal birth.

Population or Sample

64 simulated operative vaginal births.

Methods

A bespoke fetal mannequin with pressure sensors around the head and neck was used to investigate pressure applied over the head during 64 simulated births using the BD Odon Device, non-rotational forceps and the Kiwi ventouse.

Main Outcome Measures

Peak pressure on the fetal face and lateral aspects of the head during correct use of the BD Odon Device and forceps. Peak pressure on orbits and neck during misplacement of the BD Odon Device and forceps.

Results

When correctly sited and using 80kPa inflation pressure on the cuff, the BD Odon Device generated a lower peak pressure on the fetal head than forceps (83kPa vs 146kPa).
When instruments were purposefully misplaced over the orbits the BD Odon Device generated a lower peak pressure on the orbits than forceps (70kPa vs 123kPa). When purposefully misplaced over the neck the BD Odon Device, compared to forceps, generated

a greater peak pressure on the anterio-lateral aspect of the neck (56kPa vs 17kPa) and a lower peak pressure on the posterior aspect of the neck (76kPa vs 93kPa) than forceps.

Conclusions

In simulated assisted vaginal birth with correctly placed instruments the peak pressure exerted on the fetal head by a BD Odon Device is lower than pressure exerted by non-rotational forceps.

5.2 Introduction

Neonatal complications of OVB can be related to pressure exerted by the instrument on the fetal head required to complete the birth. While the pressure exerted on a fetal head is often related to the amount of traction applied by the accoucheur,

Specific adverse events that are established as being likely to be directly correlated to the amount of pressure exerted are those that relate to compression of sensitive fetal structures including the skin, facial nerve, cranial bones and eye. In addition, although no studies have attempted to specify the exact mechanism of injury, it is reasonable to assume that the amount of pressure experienced by the fetal skull is likely to contribute to extra and intracranial bleeds.

The incidence, severity and contributing factors of these events are briefly discussed below.

5.2.1 Soft tissue and bony injuries

5.2.1.1 Scalp/facial skin injuries

Bruises, lacerations, cuts and breaks to the skin can occur after both forceps and ventouse births – the most recent Cochrane review found a rate of 17% in all forceps births, and 11% in all pooled ventouse births – within this there was substantial variation based on the characteristics of the cups used – for example, the rate was higher for metal cup ventouse (Bird's, Malstrom) than soft cups (Silastic) (41% vs 29%) (11).

5.2.1.2 Facial nerve palsy

Facial nerve palsy is caused by compression of the facial nerve as it passes over the relatively incompressible temporal or zygomatic bones of the skull. Facial nerve palsy can occour after forceps birth (rates of 2.9 to 5/1000 forceps births have been reported) (76), although most case series report the substantial majority of facial nerve palsies occurring following spontaneous delivery (139). Moreover, almost all cases resolve within 24 days, with no lasting effects (140).

5.2.1.3 Ocular injury

Damage to the eye from OVB is usually described as compression of the eye by a mis-placed forceps blade, causing a rupture in Descemet's membrane on the posterior aspect of the cornea. Although relatively uncommon (one series of 11 cases over 17 years at one tertiary center described a rate of 2.4/1000 forceps birth) (77), the majority of cases are minor and self-limiting with no impact on long-term vision. However, more serious damage can occur – a significant rupture of the Descemet's membrane can cause immediate loss of sight (141), as well as long-term astigmatism and corneal scarring, and may require corneal transplantation (70,142,143).

5.2.1.4 Cranial fracture

Rates of cranial fracture are difficult to determine as most fractures are linear fractures and are minor and not diagnosed unless purposefully screened for (144). Moreover, treatment of linear fractures is often not required (144,145), with surgical intervention only being required if neurological deficit is present (81).

However, robust data does exist on the frequency of death secondary to significant skull fracture in the UK – in their 2005 review of all UK births from 1994 to 1995, O'Mahoney et al. found an absolute rate of 0.031/1000 births (78). All cases of significant skull fracture leading to death were associated with difficult operative births, using both ventouse and forceps.

5.2.2 Cranial vascular injuries

Cranial vascular injuries in the peripartum period can take the form of cephalohaematoma, subgaleal, subdural, subarachnoid, intraparenchymal and intraventricular heamorrhage. Of these, cephalohaematoma and subgaleal haemorrhage are thought to be related to pressure on the fetal skull, while subdural, subarachnoid, intraparenchymal and intraventricular haemorrhage are generally not.

5.2.2.1 Cephalohaematoma

Cephalohaematoma is a collection of blood underneath the periosteum of the cranial bones, caused by rupture of the bridging blood vessels, due to the application of direct traction and sheering forces to the scalp. The collected blood is restricted by the suture lines of the cranial bones, and so potential volume is limited. This self-tamponadeing mechanism means that clinically significant hypovolaemia or hypotension are rare (80), and almost always resolves with three weeks (81). Cephalohaematoma occurs in one to two percent of spontaneous vaginal births, four percent of forceps births and six to ten percent of ventouse births (81).

5.2.2.2 Subgaleal haemorrhage

Subgaleal haemorrhage (SGH) is caused by rupture of the emissary veins between the cranial periosteum and the scalp aponeuroses. This occurs when direct (either positive or negative) pressure on the scalp pulls the scalp aponeurosis from the cranial periosteum. As there are no anatomical constrictions on the potential subgaleal space, significant volumes of blood (up to 260ml) can extravasate into this space, resulting in hypovolaemia, hypotension, encephalopathy and coagulopathy (84,146) – of note, while some previous studies suggested that coagulopathy may be a causative factor in SGH (85), more recent case reviews have supported the notion that the coagulopathy found in some cases of SGH is a response to the pre-existing bleed, rather than its proximate cause (82,84) . Although population-level incidence estimates are lacking, rates of 0.44/1000 following spontaneous births, 1/1000 following forceps births and 5.9/1000 following ventouse births are widely agreed (82,83). While absolute mortality is hard to determine, some case reviews have reported death rates of 25% of those babies that are admitted to NICU due to SGH alone (85). National bodies continue to regard SGH as a major risk to neonates - it was in response to a significant 5-fold rise in deaths in the previous 15 years from SGH that the FDA issued its Public Health Advisory notice calling for caution when using ventouse devices in 1998 (34).

While there is speculation that softer cups (capable of applying less traction and less pressure) may result in lower levels of SGH, no studies have assessed this question directly, and the latest Cochrane review was unable to comment given the absence of any applicable data (11).

5.2.2.3 Intracranial bleeds

Intracranial bleeds (subarachnoid, subdural, intraparenchymal and intraventricular haemorrhage) are not thought to be due to physical pressure on the fetal head (in the absence of significant skull fracture) (80). Although this is intuitive given the presence of the fetal skull bones between any instrument that may compress the structures in question, it is also supported by population-level data from Werner et al., who examined all births within New York City over eight years from 1995 to 2003, and found no significant differences in rates of intraventricular haemorrhage between forceps, ventouse and Caesarean births (147). Furthermore, in their examination of all births in California between 1992 and 1994, Towner et al. found no difference in the rate of subdural haemorrhage between forceps, ventouse and Caesarean sections performed in labour (148).

Taken together, many of these complications (soft tissue, bony and vascular) are likely to be due to excess pressure exerted either directly or tangentially (as a sheering force) on the fetal head. It is axiomatic that any attempt to reduce the amount of pressure will reduce the likelihood of these complications. While this could be achieved through the application of less traction force using existing instruments, this poses the risk of reducing the effectiveness of the instruments for delivery and increasing the failure rate. A contrary strategy would be to increase the contact surface area of an instrument while keeping the traction force the same, thus reducing the contact pressure but not the likelihood of successful birth. Although this approach is intuitive, any new such instrument should be studied in simulation to determine the actual pressure experienced by the fetal head, and compared to that exerted by existing instruments.

The BD Odon Device is a new device being developed for OVB. The BD Odon Device consists of an inflatable circular air cuff attached to a thin circumferential polyethylene sleeve. A plastic applicator places the air cuff and sleeve into the birth canal, past the widest diameter of the fetal head. The air cuff is inflated, and the applicator removed. During maternal contractions the accoucheur applies traction to the sleeve, to expedite the birth.
The use of an air cuff positioned circumferentially around the fetal head as the 'anchor point' for traction has the potential to reduce fetal injury when compared to forceps. Pressure applied to the fetal head during birth may be more evenly distributed than pressure by forceps and therefore a lower risk of injury might be expected. Similarly, the wider distribution of pressure, and lack of negative pressure, may also reduce the risk of adverse outcomes such as subgaleal haemorrhage and cephalohaematoma associated with the use of ventouse. However, the possibility of the air cuff slipping down around the fetal

neck and occluding the carotid arteries needs to be evaluated, and a determination of the pressure over the anterio-lateral aspect of the neck should be made in order to evaluate the risk of the BD Odon Device causing a clinically significant compression of the carotids.

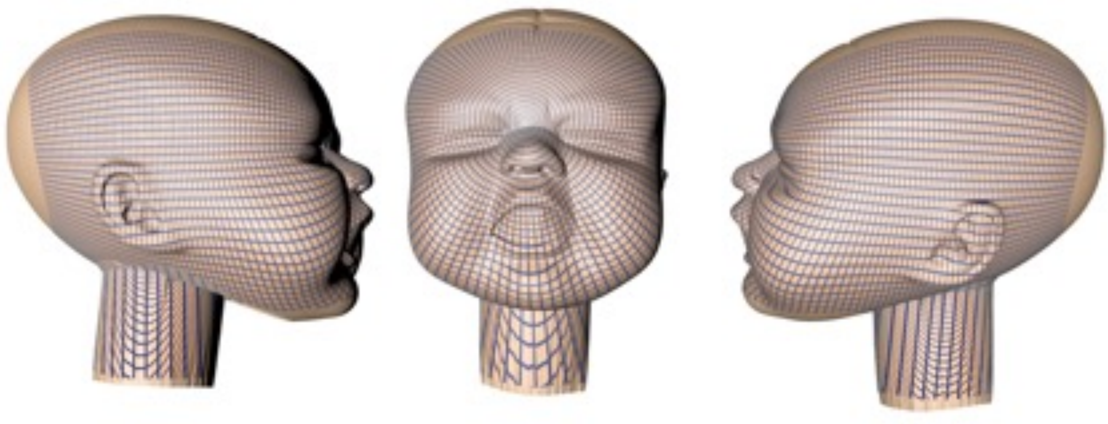
We developed a simulation model to study the pressure and force applied across the fetal head and neck during OVB. The model head was used to compare pressures on the fetal head in births using (i) non-rotational forceps, (ii) Kiwi ventouse and (iii) the BD Odon Device.

5.3 Methods

5.3.1 Development of a fetal mannequin to measure dynamic pressure changes during simulated operative vaginal birth

A bespoke fetal mannequin was designed and manufactured by a multi-professional team of obstetricians, midwives, engineers and model makers. A PROMPT Flex® fetal mannequin was adapted. Pressure sensors (Tekscan®, Boston, Massachusetts, USA) were mounted against a bespoke modelled fetal skull and neck. Three pressure sensors (Tekscan Pressure Mapping Sensor 5101: sensor pad dimensions = 111.8mm x 1118mm, thickness 0.102mm; 1,936 sensels; sensel density = 15.5 sensels/cm^2) covered the majority of the fetal skull including the entirety of the face and the lateral aspects of the head. These locations are shown in Figure 5-1.

Figure 5-1. Cloation of pressure sensors over model fetal head



An additional pressure sensor (Tekscan Pressure Mapping Sensor 6300: sensor pad dimensions = 33.5mm x 264.2mm, thickness 0.102mm; 2,288 sensels; sensel density = 25.8

sensels/cm^2) was placed around the fetal neck. The fetal neck was modified with the addition of a silicone 'collar' to an anterio-posterior diameter of 58mm, equivalent to the 50th centile of fetal neck diameters at 40 weeks gestation (149). Moulded silicone representing features of the fetal face (nose, mouth, orbits and ears) and scalp skin (5mm thick) was positioned over the pressure sensors to simulate a fetal head. The fetal mannequin had a bi-parietal diameter (BPD) of 96mm, to simulate an average-sized term baby (BPD on 50th centile of 97mm) (150). A calibration device (Tekscan PB15C) was used to equilibrate, calibrate and zero all pressure sensors prior to each use. An example of the model fetal head with pressure sensors under the silicone skin (but not the neck) is shown in Figure 5-2**.**

Figure 5-2. Pressure sensors in-situ under silicone skin, anterior and lateral views

5.3.2 Simulation of operative vaginal births

The bespoke pressure monitoring fetal mannequin was used with a standard PROMPT Flex® maternal mannequin to enable the simulation of operative vaginal births.

Chapter 5 - Simulation of pressure on a model fetal head and neck associated with the use of forceps, Kiwi ventouse and the BD Odon Device

A series of simulated OVBs using the BD Odon Device, Kiwi ventouse and non-rotational forceps were performed by a single operator (SO'B). The air cuff of the BD Odon Device was inflated to 60kPa and 80kPa. This is the expected pressure range that will be used in-vivo. The peak pressure over the face (right orbit, left orbit, nose and chin) and lateral aspects of head were measured in 40 simulated births (cephalic presentation, direct occipito-anterior, vertex 2cm below the ischial spines) in which either a BD Odon Device (cuff inflation pressure 60kPa n = 10 or 80kPa n =10), non-rotational forceps (n=10) or Kiwi ventouse (vacuum pressure 70N) (n=10) were correctly applied and used to complete the birth of the fetal model in the standard manner.

Peak pressure exerted on sensitive fetal structures (orbits and neck) were measured throughout birth in an OA position at station 2cm below the ischial spines in 24 non-standard scenarios: (i) with the BD Odon Device cuff placed purposefully over the orbit and inflated to 60kPa (n = 3) (ii) with the BD Odon Device cuff placed purposefully over the orbit and inflated to 80kPa (n = 3) (iii) with non-rotational forceps placed purposefully over the orbit (n = 3) (iv) with the BD Odon Device cuff placed purposefully around the neck and inflated to 60kPa (n = 5) (v) with the BD Odon Device cuff placed purposefully around the neck and inflated to 80kPa (n = 5) and with non-rotational forceps placed correctly on the fetal head (n = 5). Pressure data was initially captured and analysed using the proprietary iScan® program (Tekscan, Boston, Massachusetts, USA). Results are presented using descriptive statistics only. As sample sizes were small for each group (maximum n = 10), no inferential statistics were used. Results are presented with a mean value and the complete range of data.

5.4 Results

Sixty-four simulated operative vaginal births were performed (Table 5-1).

Table 5-1. Summary of simulations performed

Instrument	Position	Inflation pressure (kPa)	Instrument placement	Area analysed	Number of births
BD Odon Device	OA	60	Correct	Face	10
	OA	80	Correct	Face	10
	OA	60	Orbit	Face	3
	OA	80	Orbit	Face	3
	OA	60	Neck	Neck	5

	OA	80	Neck	Neck	5
Forceps	OA		Correct	Face	10
	OA		Orbit	Face	3
	OA		Correct	Neck	5
Kiwi ventouse	OA		Correct	Face	10
				Total births	64

Data are presented as means with ranges, as they were normally distributed (assessed using simultaneously Kurtosis statistics and the coefficient of skewness of the variable distribution as well as the qq plot and pp plot of this distribution).

5.4.1 Pressure over fetal face, lateral aspects of head, orbits, nose and mentum

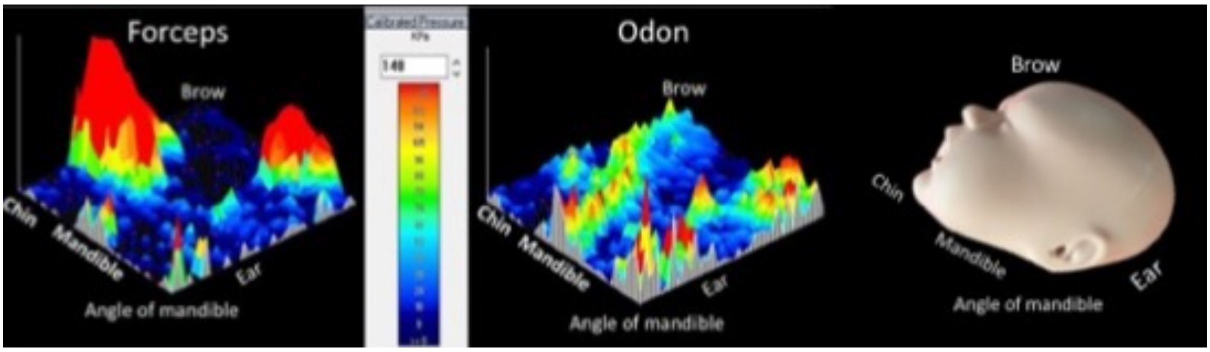
Mean peak pressures over fetal face and lateral aspects of the head are shown in Table 5-2.

Table 5-2. Mean peak pressure generated during correct placement of instruments

	Mean peak pressure generated (kPa) [range]			
	BD Odon Device, 80kPa inflation pressure n = 10	**BD Odon Device, 60kPa inflation pressure n = 10**	**Non-rotational forceps n = 10**	**Kiwi ventouse n = 10**
Lateral aspect of head	83 [62 to 111]	109 [82 to 148]	146 [108 to 154]	79 [66 to 90]
Face	106 [85 to 140]	99 [80 to 113]	108 [90 to 123]	96 [83 to 105]
Orbits	67 [27 to 109]	47 [8 to 94]	24 [9 to 45]	19.2 [9 to 30]
Nose	43 [2 to 115]	81 [49 to 129]	78 [56 to 109]	88 [69 to 105]
Mentum	30 [3 to 74]	60 [36 to 92]	38 [18 to 50]	44 [20 to 104]

The mean peak pressure over the lateral aspects of the fetal head was greater using non-rotational forceps (146kPa) compared to the BD Odon Device (109kPa at 60kPa air cuff pressure and 83kPa at 80kPa air cuff pressure) and Kiwi ventouse (79kPa). The difference in magnitude of these applied pressures over the lateral aspects of the head is illustrated in Figure 5-3.

Figure 5-3. Illustrative example of pressure differences generated over model fetal face between Odon Device and forceps



Mean peak pressures over the fetal face was comparable between the simulated births performed with non-rotational forceps (108kPa), Kiwi ventouse (96kPa) and BD Odon Device with cuff inflation pressure of 60kPa (99kPa) and 80kPa (106kPa).

Mean peak pressures over the orbits were greater using the BD Odon Device at both 60kPa and 80kPa cuff inflation pressures (47kPa and 67kPa respectively) than non-rotational forceps and Kiwi ventouse (24kPa and 19kPa respectively).

Mean peak pressures over the nose were lower using the BD Odon Device at 80kPa compared to all other scenarios, where the mean peak pressures were broadly comparable (Table 2).

Mean peak pressures over the mentum were comparable using the BD Odon Device at 80kPa inflation pressure (30kPa), non-rotational forceps (38kPa) and Kiwi ventouse (44kPa) and higher in scenarios using the BD Odon Device at 60kPa inflation pressure (60kPa).

5.4.2 Pressures exerted when devices are incorrectly sited

Three simulated births were performed with the BD Odon Device air cuff purposefully incorrectly sited over the left orbit and inflated to 60kPa, and a further three simulated births with the air cuff inflated to 80kPa. Peak pressures over the left fetal orbit were compared to three simulated births in which the non-rotational forceps were also incorrectly sited to lie over the left fetal orbit. It was only possible to perform three births for each scenario due to sensor degradation during these tests, so robust statistical comparison is not possible. However, the measurements suggest that incorrectly placed forceps generate substantially greater mean peak pressure over the fetal orbit (123kPa) than an incorrectly positioned BD Odon Device inflated to 60kPa or 80kPa (60kPa and 70kPa respectively) (Table 5-3).

Table 5-3. Mean peak pressure generated during incorrect placement over orbit

	Mean peak pressure generated (kPa) [range]		
	BD Odon Device, 80kPa inflation pressure n = 3	**BD Odon Device, 60kPa inflation pressure n = 3**	**Non-rotational forceps n = 3**
Left orbit	60 [47 to 79]	70 [68 to 72]	123 [121 to 123]

The air cuff of the BD Odon Device was purposefully placed around the fetal neck (50mm below the fetal chin) and inflated to 60kPa and 80kPa. Five OVBs were performed with the fetus in a direct OA position at each inflation pressure. A comparison of applied peak pressure was made with five non-rotational forceps births (Table 5-4). Forceps tended to exert a higher median peak pressure on the posterior aspect of the fetal neck (94kPa) when compared to BD Odon Device with the cuff inflated to 60kPa (87kPa) and 80kPa (76kPa). However, the median peak pressure applied to the anterio-lateral aspects of the fetal neck (the likely location of the fetal carotid arteries) by an BD Odon Device at 60kPa (59kPa) and 80kPa (56kPa) inflation was greater than that generated with non-rotational forceps (17kPa).

Table 5-4. Mean peak pressure generated during incorrect placement of instruments over neck

	Mean peak pressure generated (kPa) [range]		
	BD Odon Device, 80kPa inflation pressure n = 5	**BD Odon Device, 60kPa inflation pressure n = 5**	**Non-rotational forceps n = 5**
Antero-lateral aspects of neck	56 [19 to 89]	59 [32 to 97]	17 [5 to 32]
Anterior aspect of neck	44 [33 to 76]	38 [27 to 51]	20 [6 to 38]
Posterior aspect of neck	76 [48 to 106]	87 [63 to 101]	93 [77 to 109]

5.5 Discussion

5.5.1 Main Findings

The BD Odon Device, when correctly sited, generates less peak pressure on a model fetal face than correctly sited forceps, but higher peak pressure than Kiwi ventouse. The mechanism of action of the Kiwi ventouse, whereby there is no instrument in contact with the face or lateral aspect of the head, clearly explains the lower pressures for this instrument. When incorrectly sited, the BD Odon Device generates less pressure on vulnerable facial structures (the orbit) than forceps.

When the BD Odon Device was purposefully placed around the neck (previous simulation work has demonstrated that this is unlikely to occour), it generates more pressure over the anterior and antero-lateral aspects, but less pressure over the posterior aspect of the neck than forceps.

5.5.2 Interpretation

The BD Odon Device generated lower levels of peak pressure over the lateral aspects of the fetal head than forceps, but higher levels than Kiwi ventouse. This is biologically plausible. Forceps have a much lower instrument surface area in contact with the fetal head (the blades) than the BD Odon Device (the circumferential air cuff) hence identical traction forces will result in lower pressure peak pressure exerted by the Odon Device when compared to forceps. It is therefore plausible that the risk of neonatal injuries specifically associated with high peak pressures, such as facial nerve palsy, scalp injury, skull fracture and bruising (11) are likely to be lower in OVBs using the BD Odon Device than those conducted using forceps. The low pressure detected on the lateral aspects of the head during a Kiwi ventouse birth is in-keeping with the birthing mechanism and lack of contact of the instrument with the lateral aspects of the fetal head.

Direct pressure to the orbit during birth can result in serious and permanent ophthalmic injuries (70). The peak pressure generated by the BD Odon Device, at both inflation pressures of 60kPa and 80kPa, when placed directly over the orbit was substantially lower than that generated by forceps – this is likely to correlate to lower rates of trauma to the face during birth if the BD Odon Device is incorrectly sited compared to incorrectly sited forceps.

The BD Odon Device generated lower peak pressure over the posterior aspect of the neck compared to forceps. This may reflect the mechanism in which a baby in the OA position extends its neck as it negotiates the pelvic curve. Pressure is exerted on the posterior aspect of the neck as the fetus lies directly beneath the pubic symphysis, acting as a locus around which the fetal head extends. However, when a baby is delivered with the assistance of a BD Odon Device that has been purposefully misplaced around the fetal neck the air cuff rests between the posterior aspect of the neck and the pubic symphysis and appears to act as a cushion, redistributing pressure around the circumference of the neck.

We acknowledge that the simulated pressure readings cannot be a true reflection of the exact pressures exerted in clinical practice. However, the relative degree and distribution of pressures in vivo are likely to be similar to those we have observed in simulation. This simulation study suggests that the BD Odon Device generates approximately half the peak pressure generated by the forceps, with pressure distributed across a wider area i.e. there is less point pressure.

The clinical significance of the observed pressure on the anterior portion of the neck when the BD Odon Device is purposefully misplaced is unclear. Animal studies and clinical observation of 48 births in healthy volunteers in Argentina suggest the BD Odon Device is extremely unlikely to be placed around the fetal neck. Reported mean systolic blood pressure of term neonates is 72.6 (SD 9.0) mmHg (151) therefore if a pressure of 59kPa was exerted on the fetal neck by a misplaced BD Odon Device the systolic circulation through the carotid arteries could be occluded. While this pressure is sufficient to be able to theoretically occlude the carotid arteries, studies of complete carotid arterial occlusion in animals did not demonstrate a significantly reduced and sustained reduction in cerebral perfusion (152).

The BD Odon Device does not generate negative pressure on the fetal head, reducing the likelihood of adverse outcomes such as subgaleal haemorrhage or cephalohaematoma being associated with the use of a BD Odon Device when compared to vacuum assisted births.

5.5.3 Strengths and Limitations

This is the first study to attempt to quantify the pressures exerted on a baby's head and face during OVB and the methodology is necessarily pragmatic.

No statistical inferences were made between scenarios. As low numbers of individual observations were made within each group (maximum n = 10), statistical comparison would not be useful or allow for further interpretation that could not be gained from the raw data. We used a modified version of the PROMPT Flex® Force Monitoring birthing simulator with bespoke fetal heads incorporating pressure sensors. The pressure sensors have previously been employed to quantify pressures generated using forceps made from novel materials (153). We acknowledge that given the complexities of the birthing process, and the inherent limitations of any simulation-based modeling, our results are unlikely to be quantifiably reproducible in-vivo. However, the results are likely to be internally consistent and reflect the location and broad relationships in the pressures exerted by the BD Odon Device, forceps and Kiwi ventouse.

We have not been able to quantify negative pressures, or replicate the chignon associated with ventouse births. However, due to its mechanism of action we are confident that the BD Odon Device will not generate any negative pressure on the fetal head and therefore will not cause a chignon. It is therefore unlikely that the most serious outcomes generated by negative pressure (subgaleal haemorrhage or cephalohaematoma), or those associated with movement of the cup over an established chignon (scalp abrasion/avulsion) will occur following births conducted using the BD Odon Device.

5.6 Conclusion

The BD Odon Device generates lower peak pressure than non-rotational forceps during simulated birth and does not exert a negative pressure required to perform a vacuum assisted birth. It is therefore likely that the BD Odon Device will be associated with lower adverse outcomes related to both peak pressure (bruising, facial nerve palsy, skull fracture) and negative pressure (subgaleal or retinal haemorrhage and cephalohaematoma, scalp abrasion/avulsion) compared to currently available instruments (forceps and ventouse).

Chapter 6 Development of the design and training of the BD Odon Device: a human factors engineering process

6.1 Abstract

Objective

To (i) determine how intended users interact with and use the BD Odon Device in simulation, (ii) use these findings to progressively alter the design of the BD Odon Device and (iii) validate that these changes have improved the ability of practitioners to use the BD Odon Device

Design

Human Factors evaluation study

Setting

Simulation suite designed to mimic delivery room.

Population or Sample

390 simulated operative births, performed by 100 practicing clinicians.

Methods

Simulated operative vaginal births performed using the BD Odon Device and Instructions For Use were subjected to four human factors evaluations. Following each evaluation, findings were reviewed and the design of the BD Odon Device and Instructions For Use were modified.

Main Outcome Measures

Successful performance of steps required to perform an operative vaginal birth using the BD Odon Device in accordance with provided training and Instructions For Use.

Results

Using version one of the BD Odon Device, and following exposure to face-to-face training and written instructions, 25% of accoucheurs were able to successfully perform a simulated operative vaginal birth. In the final evaluation, following device design and training material alterations, all accoucheurs were able to successfully perform a simulated operative vaginal birth using version four of the BD Odon Device.

Conclusions

Chapter 6 - Development of the design and training of the BD Odon Device: a human factors engineering process

Human factors evaluations have enabled a multi-professional device and training materials design team to alter the design of the BD Odon Device and the Instructions for Use in an evidence-based fashion. This process has resulted in a device which has a predictable and likely safe pattern of use.

Chapter 6 - Development of the design and training of the BD Odon Device: a human factors engineering process

6.2 Introduction

Operative vaginal birth is an important skill that can improve outcomes for mothers and their babies (6). However, performing an operative vaginal delivery is a complex, time critical technical skill and the misuse of forceps or vacuum can lead to significant injury to the mother and/or her baby (154). Such concerns led to the FDA in the USA to releasing a Public Health Advisory Paper explaining the need for caution when using vacuum assisted delivery devices (34). Similar concerns have been expressed about the use of forceps (16). While forceps and vacuum are not inherently dangerous, inappropriate patient selection, level of technical skill or poor team working in using the instrument can all interact and have a significant effect on their safety, and therefore on poor uptake around the world, especially in LMICs (49,107). Within this context, the introduction of a new device for OVB is a reasonable strategy to try and promote better outcomes for women and babies who encounter complications in the second stage of labour (8,50).

The introduction into clinical practice of a new medical device to expedite vaginal birth is complex and requires detailed investigation to identify and mitigate potential risks. Specific questions that should be answered by any design team include; how is the device used, how is the device best used and how do clinicians train to use the device? The unique features of the BD Odon Device (e.g. air chamber and sleeve) seem to offer advantages in clinical practice but the novelty of the design means that the technique required for the BD Odon Device is markedly different from those employed during a forceps or vacuum assisted delivery. Therefore, before it is introduced into clinical practice it is crucial to ensure that accoucheurs use the BD Odon Device in a safe and effective manner. Ideally, the use of the BD Odon Device should be understandable, intuitive and reproducible. Moreover, the BD Odon Device and IFU should demonstrate that they can be used by representative users without producing patterns of failures that could result in poor clinical outcomes or harm to clinicians.

Human Factors Engineering (HFE) focuses on the interactions between people and devices and is used to ensure that medical devices are as safe, reliable and effective as possible (155). Human factors evaluations are used to refine and improve the user-device interface. This interface includes all components with which users interact with the device; preparing the device for use (e.g. unpacking and set up) and using the device (e.g. how users perceive and interpret the information from the device, make decisions about what to do, and manipulate the device during use). Human factors evaluations provide evidence to ensure that a device does not lead to failures and that the risk controls made by the design team, by altering the device or the supporting training materials are effective. The most important goal of the human factors engineering process is to minimize use-related hazards and risks and thus improve safety (155).

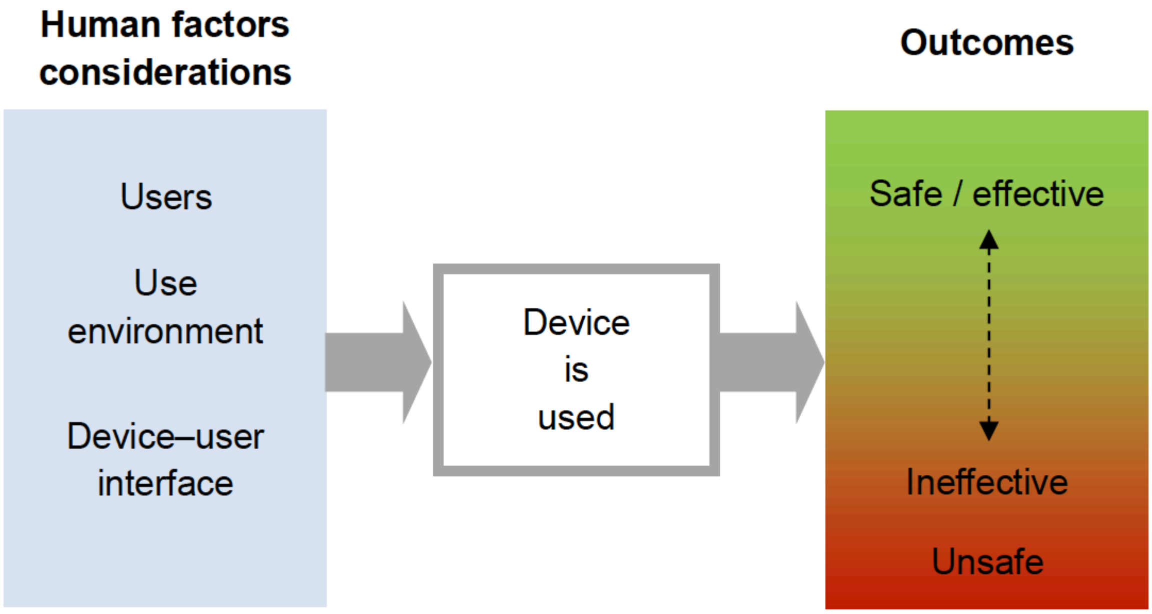
Notably, since the commencement of this thesis project, the relevant regulatory body within the UK, the Medicines and Healthcare products Regulatory Agency (MHRA), has issued new guidance which specifically states that new medical devices should be analysed within the context in which they are intended to be used. This is in order to "reduc(e), as far as possible, the risk of use error due to the ergonomic features of the device and the environment in which the device is intended to be used (design for patient safety), and (include) consideration of the technical knowledge, experience, education and training and where applicable the medical and physical conditions of intended users (design for lay, professional, disabled or other users)". This need can be met by the utilisation of HFE studies (156).

6.2.1 Human factors engineering

Human factors is the scientific discipline concerned with the understanding of interactions among humans and other elements of a system, and the activity that applies theory, principles, data and methods to design in order to optimize human well-being and overall system performance (157). Within this, human factors engineering is human factors application of knowledge about human behaviour, abilities, limitations, and other characteristics to the design of medical devices systems and tasks to achieve adequate usability (156).

Human factors engineering examines the outcome following the use of the device, taking into account all potential drivers, including how users behave, their environment and the device itself. This process is illustrated in Figure 6-1.

Figure 6-1. Human factors affect outcomes of using medical devices



* Adapted from FDA's 'Applying Human Factors and Usability Engineering to Medical Devices' guidance February 2016 (158)

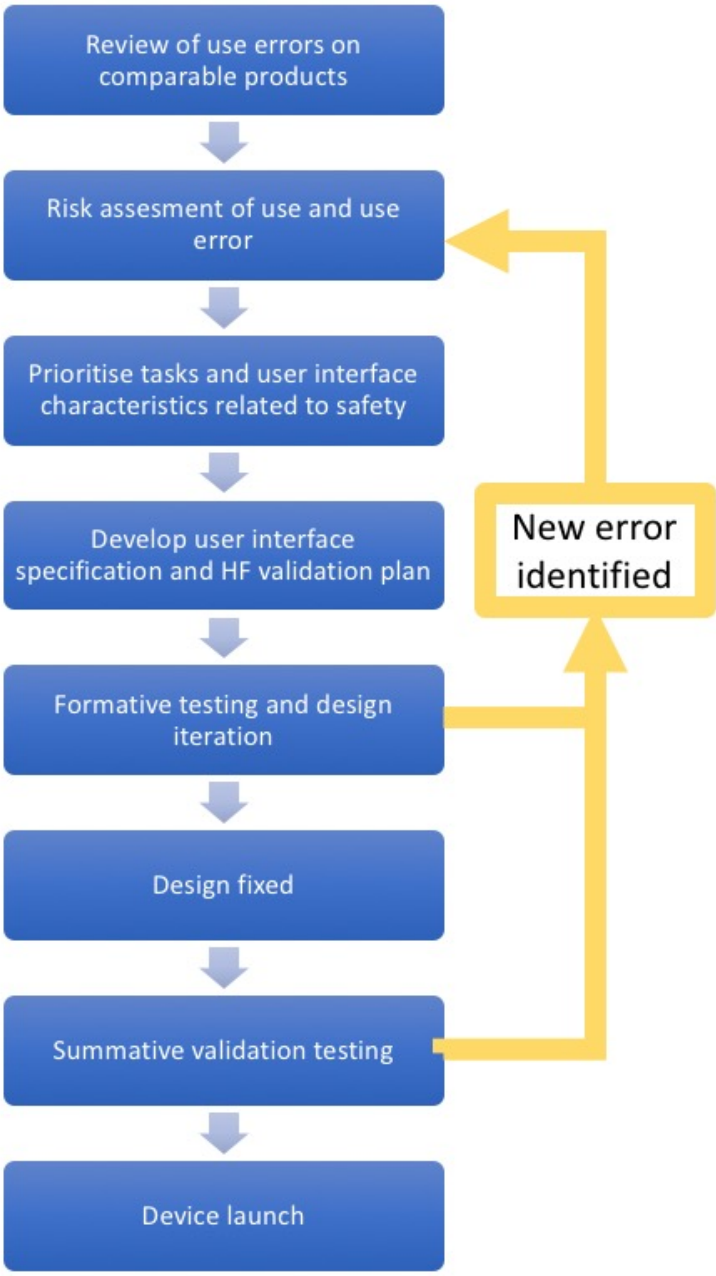
Design teams can utilise human factors engineering to systematically identify risks inherent within the design or training provided with any new device – this then affords the design team the opportunity to put in place mitigations or alterations to an existing design or training package to reduce these risks.

Human factors engineering should ideally be an iterative process with multiple stages of formative evaluations, with identified risks mitigated by purposeful changes to the device design and/or training provided. Following each formative round, risks should be analysed and a determination made as to whether or not they have been reduced to an acceptable level.

Following a formative round that has demonstrated no outstanding critical risks, a summative validation evaluation should take place. The summative validation evaluation should have a pre-specified level of acceptable performance for all domains of the use of the device, and should only be deemed as successful if all thresholds are met.

This process is illustrated in Figure 6-2.

Figure 6-2. The human factors engineering process



* Adapted from MHRA's Human Factors and Usability Engineering – Guidance for Medical Devices Including Drug-device Combination Products, September 2017 (156)

A significant benefit of using human factors engineering is that, because the process analyses outcomes following the use of the device after training has been provided, it enables analysis of the training rather than just the device alone. This avoids the problem of having to adjust for different devices or technology that may be introduced during later attempts to analyse the effect of training alone in clinical practice. This process also provides an evidence base for any training programme developed in this way – this does not currently exist for some of the highest profile obstetrics practical skills training packages, from device-specific packages such as the 'Vacca 5-step technique' for the Kiwi ventouse to the all types of OVB RCOG-endorsed ROBuST course (36).

6.2.1.1 Participants

Participants in human factors engineering cycles should be representative of the likely user groups. Groups can be assigned by levels of experience, profession or other identifiable characteristic, but this division must be of relevance to the later user groups once the device is in clinical practice. Greater numbers of participants from a specific group will increase the likelihood of identifying all possible user errors that may occur – previous work has found that a sample size of 15 participants per group is likely to identify 97% of all use errors, and since the commencement of this thesis, this has been adopted as an industry standard (156,158). While smaller sample sizes are acceptable for formative rounds of HFE, a summative HFE validation test should contain at least 15 participants per group of interest (158). The percentage of user errors detected in various group sizes is shown in Table 6-1.

Table 6-1. Percentage of Total Known Usability Problems Found in 100 Analysis Samples

No. of users	Min. % found	Mean % found	*SD*	*SE*
5	55	85.55	9.2	0.92
10	82	94.69	3.2	0.32
15	90	97.05	2.1	0.21
20	95	98.4	1.6	0.16
30	97	99.0	1.1	0.10

* Adapted from Faulkner L. Beyond the five-user assumption: Benefits of increased sample sizes in usability testing. Behaviour Research Methods, Instruments, & Computers. Springer-Verlag; 2003;35(3):379–83 (159).

6.2.1.2 Current use

HFE has been used in the development of other medical devices relevant to a new device for OVB. Studies have been carried out on new devices which are designed to be used by users of the current standard device, of all levels of experience. HFE have been used in, for example, the development of a new model of naloxone auto-injecting pen, for use by experienced emergency medicine doctors, emergency department nurses, paramedics and patients, and the development of a new form of laparoscopic port, for use by novice, intermediate and expert surgeons (160,161).

Despite the clear need to structured, formal evaluation of devices for OVB and their associated training, HFE has not been used in the development of any devices within the field of OVB. This is likely to change in the future in light of recent guidance from the regulatory bodies in the US (FDA, September 2016), the UK (MHRA, September 2017) and the EU (EU, July 2017) - conducting HFE studies on new medical devices is now mandatory for manufacturers within these jurisdictions (109,156,158) – however, this was not the case at the design stage of this project, and as such this thesis represents the first use of HFE in the design and development of any device or training package within OVB.

This chapter describes the human factors evaluations conducted to determine the usability of the BD Odon Device and describes the iterative modifications to the design of device (and associated Instructions For Use (IFU) and training materials) in response to user feedback.

6.2.2 General methods

Three formative evaluations and one Human Factors Validation Test (HFVT) were conducted. Participants in the formative evaluations were practicing midwives and obstetricians from South West of England and all testing was conducted in Southmead Hospital, Bristol, UK. Participants in the validation test were recruited from 14 countries (UK, Ireland, Germany, Spain, Italy, Denmark, Egypt, Nigeria, South Africa, Kenya, Jordan, India, Nepal and Australia). Testing was conducted in Southmead Hospital, Bristol, UK, the Pump Rooms, Bath, UK, and the RCOG Annual Congress 2017, Cape Town, South Africa. Each participant performed a series of structured simulations of an operative vaginal birth using the BD Odon Device to deliver a fetal mannequin from an anatomical accurate maternal mannequin (PROMPT Flex, Limbs and Things Ltd, Bristol, UK) (Figure 6-3) (162).

Figure 6-3. A PROMPT Flex maternal and fetal mannequin

Participants were able to participate in the study if they fulfilled all of the criteria below:

(i) At least 18 years of age.

(ii) Currently employed in a clinical setting.

(iii) Able and willing to provide a signed Participant Agreement.

(iv) Able and willing to complete all study assessments.

(v) Able to read, write and follow instruction in English.

(vi) Agree to the being videoed, recorded and/or photographed.

Participants were excluded from the study and unable to take part if they did not fulfil all of the inclusion criteria listed above or if they fulfilled any of the following:

(i) Have physical conditions which would make them unable to perform study procedures.

(ii) Have discussed the details of this study or test products with BD staff or other study participants outside of the study.

(iii) Work for a medical device company.

In each simulation, the fetal mannequin was placed in a cephalic presentation, in the occipito-anterior (OA) position, with the vertex 2cm below the ischial spines. To increase the environmental validity of the simulations, all assisted births were performed in a setting design to mimic a delivery room, with the maternal mannequin lying on a delivery bed or table. All simulations and interviews were recorded on a stationary video camera (GoPro Hero4 Session, GoPro, San Mateo, California, USA) and observed by an Obstetrician (SOB), Human Factors Expert (AM), Design Engineer (DA, TS or WLL). The inventor of the BD Odon Device (JO) was present for the majority of simulations.

Participants were provided with a prototype BD Odon Device and asked to attempt to deliver the fetus using the device. Expediting birth using the BD Odon Device requires three distinct stages to be completed by the operator: (i) preparation of the device, (ii) application of the device into the correct position around the fetal head, and (iii) use of traction to deliver the fetal head. These three stages, together with the individual steps required in each stage, are outlined in Table 6-2.

Table 6-2. General list of steps required to perform an OVB with the BD Odon Device

Phase	Step
Preparation	Assess patient and determine suitability for OVB – not assessed in this study
	Open BD Odon Device packaging while maintaining sterility
	With the fastening band still intact, generously lubricate the inside and outside of the sleeve and the cup
	Lubricate birth canal
	While holding the sleeve handle gently slide the fastening band to the top of the sleeve
Application	Fold the cup and gently insert it into the vulva and check it has regained its circular shape
	Check that there is no maternal tissue trapped between the cup and the fetal head
	While gently pushing, continue inserting the sleeve and applicator into the vulva until the top of the fastening band is inside the vulva
	Open and remove the fastening band while the sleeve and applicator remains inside the vulva
	Between contractions, continue to gently insert the applicator, starting at 45º below the horizontal and following the curvature of the birth canal. Monitor progress by looking through the viewing window
	Continue to insert the device and stop when “0” appears in the viewing window
	Inflate the cuff by fully squeezing the bulb pump at least 8 times
	While protecting the perineum with one hand, use the other hand to completely withdraw the applicator and cup, leaving only the sleeve in place
	To compensate for possible reduction in cuff pressure after removing the applicator, squeeze the bulb pump 2 more times
Delivery	Grasp the sleeve handle, and during contractions pull gently and progressively following the J-shape of the birth canal
	While continue to pull gently along the J-shape of the birth canal. Confirm the fetal head is descending with pulling efforts
	Once you see the blue deflation line completely (approximately at crowning) deflate the cuff by pushing on the deflation button. Pull the sleeve handle continuing to press the deflation button following the J-shape of the birth canal
	Continue to pull the sleeve handle while pressing the deflation button to pull the fetal head until the sleeve detaches from the head
	Proceed to assist the birth of the baby as per normal procedure

At the start of rounds one, two and three (formative rounds) each participant was randomized to one of four groups: (i) using the device with no instructions for use (IFU), (ii) using the device after reading a copy of the current IFU, (iii) using the device after face-to-face training, and (iv) watching a training video. During the final validation evaluation, all participants were exposed to one-to-one training and the IFU before attempting to use the device. The individual objectives of each study varied based on the findings of the previous study and subsequent design changes made by the study team to the device and IFU, while the overall objective (to determine how participants interacted with the BD Odon Device and IFU, and to mitigate any patterns of use which would compromise the safety and efficacy of the device) remained the same.

The ability of participants to perform each phase and step was recorded after their exposure to different training materials (IFU, video and one-to-one training). A step was defined as being successfully completed if it was performed safely, correctly and in the correct sequence.

Following the simulations participants were questioned on the design of the device and their understanding of (i) the BD Odon Device, (ii) the IFU, (iii) the face-to-face training module and (iv) training video.

Following each Human Factors Evaluation, the multi-professional device development team comprising Obstetricians, Midwives, Human Factor Specialists and R&D Engineers used the study findings to iteratively modify the device and associated IFU and training materials to address any user difficulties and/or risks observed during simulations. These evidence-based changes were evaluated in the subsequent round of testing to ensure the previously uncovered user errors had been mitigated and no new risks or problems had been created. Simulations and interviews were structured in accordance with Human Factor Evaluation guidance from the FDA and the Medicines and Healthcare products Regulatory Agency (MHRA) (155,158). The study was approved by the North Bristol NHS Trust Research & Innovation Department (Study Number 3671) on 29th February 2016. As per the UK Health Departments' Governance Arrangements for Research Ethics Committees (GAfREC) this study did not require ethical approval.

6.2.3 General results

Three formative studies and a Human Factors Validation Study were undertaken. Three hundred and ninety simulated births were conducted using the BD Odon Device. In total 100 naïve participants who had not previously been exposed to the BD Odon Device participated. The demographics of the four cohorts are summarised in Table 6-3.

Table 6-3. Demographics of participants in HFE Rounds 1, 2, 3 & 4

Characteristic		Formative round 1 (n = 35)	Formative round 2 (n = 11)	Formative round 3 (n=18)	Validation round 4 (n=36)
Age					
	Mean	41.2	35.9	37.1	44.8
	Std Dev	10.8	8.1	8.7	9.9
	Range	25 to 59	26 to 52	25 to 52	32 to 69
Gender					
	Male	6 (17%)	0 (0%)	1 (6%)	11 (30%)
	Female	29 (83%)	11 (100%)	17 (94%)	25 (70%)
Handedness					
	Right	33 (94%)	10 (91%)	16 (88%)	34 (95%)
	Left	2 (6%)	1 (9%)	1 (6%)	2 (5%)
	Unknown	0 (0%)	0 (0%)	1 (6%)	
Profession					
	Midwife	15 (43%)	7 (64%)	8 (44%)	18 (50%)
	Obstetrician	20 (57%)	4 (36%)	10 (56%)	18 (50%)
Years of experience					
	4 or less	12 (34%)	6 (55%)	4 (22%)	3 (8%)
	≥5	23 (66%)	5 (45%)	14 (78%)	33 (92%)
Number of OVBs observed/performed per month					
	Mean	13.8	7	11.6	8.1
	Stan Dev	11.5	5.2	7.5	5.8
	Range	1 to 50	2 to 18	2 to 30	1 to 20
Instrument of choice (If obstetrician)					
	Forceps	10 (50%)	0 (0%)	4 (40%)	7 (39%)
	Vacuum	6 (30%)	0 (0%)	4 (40%)	8 (44%)
	No preference	4 (20%)	4 (100%)	2 (20%)	3 (17%)

The percentage of participants able to correctly perform at least 50% and 75% of the steps required in each phase (preparation, application and delivery) of the use of the BD Odon Device are provided in Table 6-4. These data are further classified by device version (version two, three or four) and type of training (no IFU, IFU alone, IFU and one-to-one training, IFU and video) and the attempt number.

Table 6-4. Ability of participants to successfully perform steps in stages of OVB using the BD Odon Device

			Percentage of participants correctly performing ≥50% and ≥75% of required steps					
			Preparation		Application		Delivery	
			≥50%	≥75%	≥50%	≥75%	≥50%	≥75%
Round 1	1st attempt	V2 device (n=11)	18	0	No participants progressed to this point			
	2nd attempt	V2 device & IFU (n=28)	89	29	29	25	29	25
	3rd attempt	V2 device & IFU & training (n=35)	97	25	100	94	100	100
Round 2	1st attempt	V2 device & IFU (n=5)	80	40	No participants progressed to this point			
	1st attempt	V2 device & IFU & video & training (n=11)	82	27	100	100	100	100
Round 3	1st attempt	V3 device & IFU (n=9)	78	78	78	78	78	78
	1st attempt	V3 device & video (n=9)	100	78	100	100	100	100
	2nd attempt	V3 device & IFU & video & training (n=18)	100	94	89	89	89	89
	3rd attempt	V3 device, exposed to all training materials (n=18)	100	100	100	100	100	100
Round 4	1st attempt	V4 device & training (n=36)	100	100	100	97	97	97

2[nd] attempt	**V4 device & training & IFU (n=36)**	100	100	100	100	94	97
3[rd] attempt	**V4 device & training & IFU (n=36)**	100	100	100	100	100	100

There was no significant difference between the ability of midwives and obstetricians to perform an operative vaginal birth using the BD Odon Device (Table 6-5).

Table 6-5. Ability of participants to perform steps in stages of OVB using the BD Odon Device by profession

		Proportion of participants correctly performing ≥50% and ≥75% of required steps					
		Preparation		**Application**		**Delivery**	
		≥50%	**≥75%**	**≥50%**	**≥75%**	**≥50%**	**≥75%**
V2 Device & IFU & training	**Midwives (n=15)**	93	27	100	87	93	93
	Doctors (n=20)	95	20	100	95	100	100
V4 Device, exposed to all training materials	**Midwives (n=18)**	89	89	100	100	100	100
	Doctors (n=18)	100	100	100	100	100	100

A detailed breakdown of participant behaviours and responses to all observed categories, questions and interviews in all rounds of HFE is set out in the Additional Data supplied with this thesis.

6.3 Formative round one (March 2016)

6.3.1 Objectives

Using simulation, the objectives of this HFE round were:

- to identify potential risks from how users interact with the BD Odon Device version two (Figure 6-4)
- to evaluate the utility of the current Instructions For Use (IFUv1, Appendix 1) to inform any necessary changes and ensure that the product has an evidence-base

Figure 6-4. BD Odon Device, version two

6.3.2 Primary outcomes

- To assess if users are comfortable using the BD Odon Device in simulated circumstances after exposure to the IFU and a brief training session
- To assess if users feel confident to use the BD Odon Device after exposure to IFU and brief training

- To assess the extent to which users are able to demonstrate the correct technique in using the BD Odon Device before and after exposure to IFU and brief training

6.3.3 Secondary outcomes

To identify:

- The steps within the procedure which are most and least likely to contribute to the successful use of the BD Odon Device
- The usefulness of an IFU to users when performing an OVB using the BD Odon Device
- How well users can recall and demonstrate individual steps for performing an OVB using the BD Odon Device after exposure to the IFU and brief training
- What level of difficulty users rate individual steps for performing an OVB using the BD Odon Device
- What level of acceptability and intuitiveness the users rate for all parts of the design of the BD Odon Device
- Any modifications to the device that may help users feel more confident in performing previously identified problematic tasks

6.3.4 Methods

This was a human factors engineering study. All participants were asked to attempt a number of simulated deliveries with the BD Odon Device on a maternal/fetal dyad (PROMPT Flex), with the baby in an OA position and station +2 spines. Participants were asked to undertake their first attempted simulated OVB in the conditions above with either no training, access to the IFU alone, or following access to the IFU and training. The steps required in this round to perform an OVB using the BD Odon Device are shown in Table 6-6. Following this first attempted birth, participants were granted access to the IFU and full training (if not given already), and undertook a second attempted OVB. Following this, participants were fully trained again, and undertook a third attempted OVB. Participants were also questioned about how comfortable and intuitive they found the device, and were tested on how well they recalled the contents of the IFU. These procedures are laid out in the study flow chart (Figure 6-5).

Figure 6-5. Round 1 flow-chart

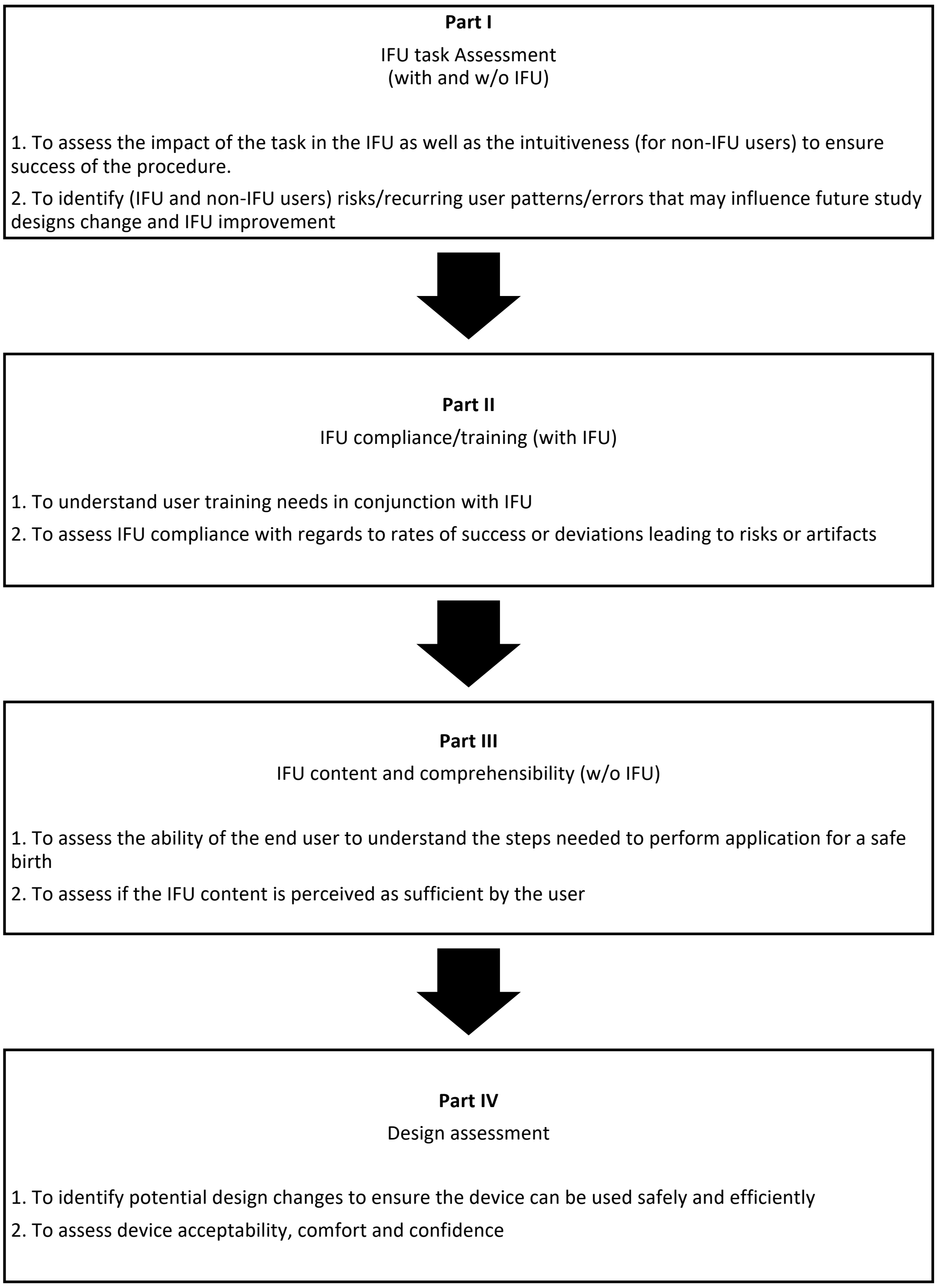


Table 6-6. Steps of performing an OVB with the BD Odon Device in HFE Round 1

Step	Description
1	Remove BD Odon Device from packaging without compromising the sterility of the device
2	With the fastening band still intact, generously lubricate the inside and outside of the sleeve and the cup
3	Lubricate birth canal
4	While holding the sleeve handle gently slide the fastening band to the top of the sleeve
5	Fold the cup and gently insert it into the vulva and check it has regained it's circular shape
6	Check that there is no maternal tissue trapped between the cup and the fetal head
7	While gently pushing, continue inserting the sleeve and applicator into the vulva until the top of the fastening band is inside the vulva
8	Open and remove the fastening band while the sleeve and applicator remains inside the vulva
9	Between contractions, continue to gently insert the applicator, starting at 45º below the horizontal and following the curvature of the birth canal. Monitor progress by looking through the viewing window
10	Continue to insert the device and stop when "0" appears in the viewing window
11	Confirm stop pushing when "0" appears in viewing window
12	Inflate the cuff by fully squeezing the bulb pump at least 8 times
13	Confirm pumps at least 8 times
14	While protecting the perineum with one hand, use the other hand to completely withdraw the applicator and cup, leaving only the sleeve in place
15	To compensate for possible reduction in cuff pressure after removing the applicator, squeeze the bulb pump 2 more times
16	Grasp the sleeve handle, and during contractions pull gently and progressively following the J-shape of the birth canal
17	While continue to pull gently along the J-shape of the birth canal. Confirm the fetal head is descending with pulling efforts
18	Once you see the blue deflation line completely (approximately at crowning) deflate the cuff by pushing on the deflation button. Pull the sleeve handle continuing to press the deflation button following the J-shape of the birth canal
19	Continue to pull the sleeve handle while pressing the deflation button to pull the fetal head until the sleeve detaches from the head
20	Proceed to assist the birth of the baby as per normal procedure

All procedures took place in a dedicated research space in The Chilterns, Southmead Hospital, Bristol. Observations from each attempted OVB using the BD Odon Device were recorded directly onto paper proformas. Each attempted birth was recorded on video by one stationary camera.

6.3.4.1 Sample

Participants were selected from four groups of maternity staff representative of the future user population for the BD Odon Device.
These were:

- Obstetricians/gynaecologists
- Midwives
- Obstetricians/gynaecologists or midwives of 5 or more years continuous experience
- Obstetricians/gynaecologists or midwives of 4 or less years continuous experience

Thirty-five participants were recruited, satisfying guidance on the minimum required in each user group to achieve saturation of adverse events in FDA guidance on human factors studies (158).

Participants were recruited from a single maternity unit in Bristol, UK. This is a busy tertiary-level centre with >6,500 births/year with a 12% instrumental birth rate. The Principal Investigator (SOB) approached participants by email and direct personal contact. Participants took part in the study outside of their employed hours. To compensate for their time participants were offered a £20 voucher for a department store, a level of compensation in line with guidance from the National Institute of Health Research (NIHR) (163).

6.3.4.2 Statistical analysis

Frequency data for outcomes is presented using descriptive statistics. No further inferential statistics were undertaken as this was a complete sample.

6.3.5 Results

Thirty-five participants undertook the study procedure. Demographics of study participants are described below in Table 6-7.

Table 6-7. Participant demographic details

Characteristic	Results

		(n = 35)
Age		
	Mean	41.2
	Stan Dev	10.8
	Range	25 to 59
Gender		
	Male	6 (17%)
	Female	29 (83%)
Handedness		
	Right	33 (94%)
	Left	2 (6%)
Professions		
	Midwife	15 (43%)
	Obstetrician	20 (57%)
Years of experience		
	4 or less	12 (34%)
	≥5	23 (66%)
Number of operative vaginal births observed/performed per month		
	Mean	13.8
	Stan Dev	11.5
	Range	1 to 50
(If obstetrician) What is your instrument of choice? (n = 20)		
	Forceps	10 (50%)
	Ventouse	6 (30%)
	No preference	4 (20%)

The experience levels of participants in each study group are described in Table 6-8.

Table 6-8. Experience of participants by occupational group

	Experienced (n=23)	Inexperienced (n=12)
Midwife (n=15)	11	4
Obstetrician (n=20)	12	8

6.3.6 Primary Outcomes

6.3.6.1 Comfort/confidence

The majority of both midwives and obstetricians reported feeling confident/comfortable or very confident/comfortable using the BD Odon Device in simulated circumstances after exposure to the IFU and brief training (Table 6-9). Only 8% participants felt somewhat not, or not at all, confident/comfortable using the BD Odon Device after exposure to the IFU and a brief one-to-one practical training session.

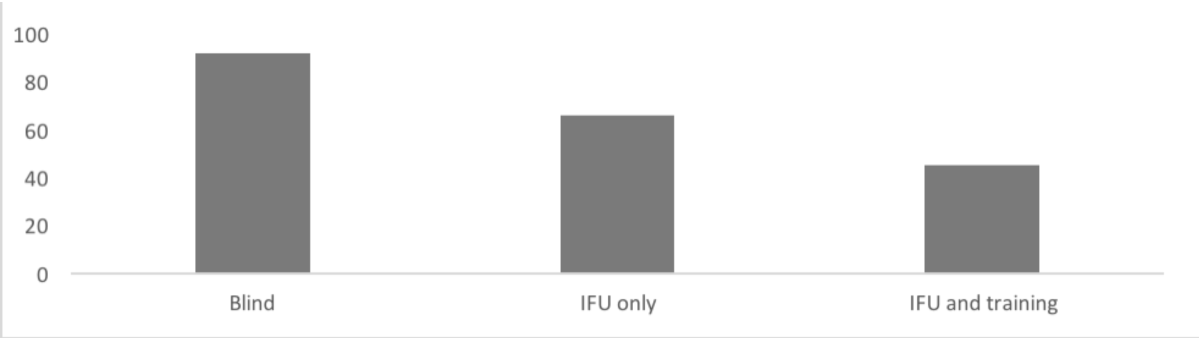
Table 6-9. Participant responses concerning comfort/confidence (after exposure to IFU and brief one-to-one practical instruction)

	Response Value (% of subgroup)								
Question	Not at all	Somewhat not	Somewhat/ neutral	Confident/comfortable			Extremely/very		
				Pooled	M/w	Obs	Pooled	M/w	Obs
How confident do you feel using the device? (n = 34)	2	1	15	16	8 (53%)	8 (40%)	0	0 (0%)	0 (0%)
How comfortable do you feel using the device? (n = 34)	0	3	5	22	9 (60%)	13 (65%)	4	2 (10%)	2 (10%)

6.3.6.2 Encountering difficulty – before and after IFU and training

Participants encountered progressively fewer difficulties in using the BD Odon Device in simulated circumstances after exposure to the IFU and even fewer difficulties were encountered after a brief one-to-one practical training session (Figure 6-6). Ninety-two percent of participants reported difficulties with applying the device before exposure to the IFU and training, 66% reported difficulties after exposure to the IFU alone, whereas only 45% of participants reporting difficulties after exposure to the IFU together with practical training.

Figure 6-6. Percentage of participants reporting difficulties in using device after IFU and training



6.3.6.3 Ability to demonstrate use of device

Following exposure to both IFU and training 32 of the 34 (94%) participants were able to successfully demonstrate the correct usage of the device. The remaining two (6%) participants were able to demonstrate the use of the BD Odon Device to some degree.

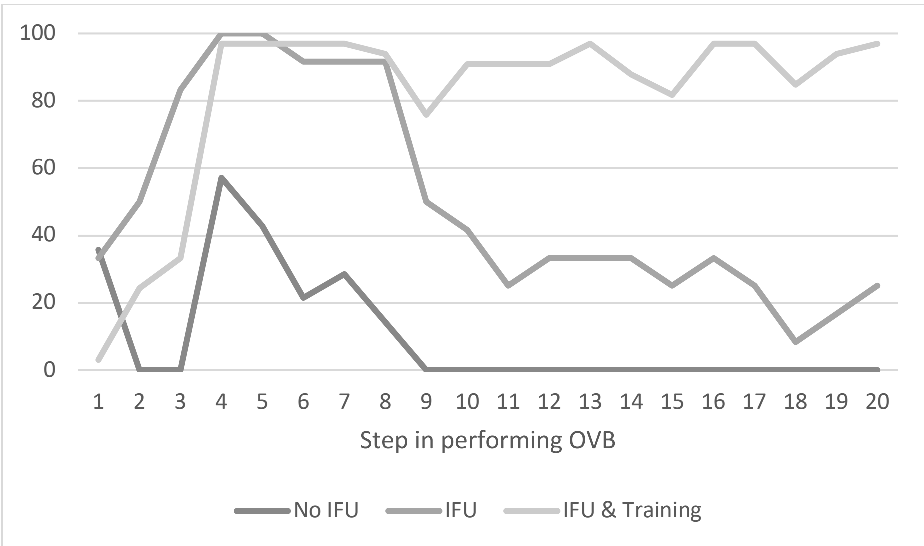
Step	Description
1	Unpack
2	Lubricate device
3	Lubricate birth canal
4	Slide fastening band
5	Insert cup
6	Check maternal tissue
7	Insert tip of device
8	Remove fastening band
9	Insert device
10	Stop at "0"
11	Confirm stop
12	Inflate cuff
13	Confirm inflation
14	Withdraw applicator
15	Re-inflate cuff
16	Pull
17	Confirm fetal descent
18	Deflate cuff
19	Detach cuff
20	Assist birth

6.3.7 Secondary outcomes

6.3.7.1 Steps of procedure most likely to succeed or fail by training level

Participants were significantly more likely to be able to progress with using the device in simulated circumstances (that is, not have to cease the procedure due to a lack of understanding/knowledge of next steps) after being exposed to the IFU. This effect was even greater after exposure to training. Following training almost all participants were able to successfully complete all 20 steps to perform a simulated OVB (Figure 6-7).

Figure 6-7. Percentage of participants able to complete each step in procedure by training level



The specific steps that participants were most likely to succeed or fail at for each training group are described in Table 6-10, Table 6-11 and Table 6-12.

Step	Description
1	Unpack
2	Lubricate device
3	Lubricate birth canal
4	Slide fastening band
5	Insert cup
6	Check maternal tissue
7	Insert tip of device
8	Remove fastening band
9	Insert device
10	Stop at "0"
11	Confirm stop
12	Inflate cuff
13	Confirm inflation
14	Withdraw applicator
15	Re-inflate cuff
16	Pull
17	Confirm fetal descent
18	Deflate cuff
19	Detach cuff
20	Assist birth

Table 6-10. Success/failure for participants without IFU

	Step(s)	Number of participants succeed/fail at this step n=14
Steps most likely to be successful		
	Lubricating sleeve	8
	Lubricating birth canal	6
	Removing device from packaging	5
Steps most likely to fail		
	Ensure spatula tips fully inserted	14
	Insert along J-shaped curve	13
	Stop pushing once "0" in window	13
	Inflate the cuff	13
	Withdraw applicator	13
	Re-inflate cuff	13
	Check for maternal tissue after inserting cup	9

Step	Description
1	Unpack
2	Lubricate device
3	Lubricate birth canal
4	Slide fastening band
5	Insert cup
6	Check maternal tissue
7	Insert tip of device
8	Remove fastening band
9	Insert device
10	Stop at "0"
11	Confirm stop
12	Inflate cuff
13	Confirm inflation
14	Withdraw applicator
15	Re-inflate cuff
16	Pull
17	Confirm fetal descent
18	Deflate cuff
19	Detach cuff
20	Assist birth

Table 6-11. Success/failure for participants with IFU

	Step(s)	Number of participants succeed/fail at this step
Steps most likely to be successful		
	Lubricate sleeve, lubricate birth canal	12
	Grip handle with viewing window uppermost	11
	Fold cup and place inside vulva	11 11
	Check for maternal tissue	
	Ensure fastening band is in place	10
Steps most likely to fail		
	Re-inflate cuff after applicator removal	9
	Stop pushing once "0" in viewing window Withdraw applicator	8 8
	Inflate the cuff	7

Step	Description
1	Unpack
2	Lubricate device
3	Lubricate birth canal
4	Slide fastening band
5	Insert cup
6	Check maternal tissue
7	Insert tip of device
8	Remove fastening band
9	Insert device
10	Stop at "0"
11	Confirm stop
12	Inflate cuff
13	Confirm inflation
14	Withdraw applicator
15	Re-inflate cuff
16	Pull
17	Confirm fetal descent
18	Deflate cuff
19	Detach cuff
20	Assist birth

Table 6-12. Success/failure for participants following brief training

	Step(s)	Number of participants succeed/fail at this step
Steps most likely to be successful		
	Deliver baby as per usual procedure	32
	Detach sleeve from fetal head	31
	Stop pushing once "0" appears in viewing window	30
Steps most likely to fail		
	Push applicator until tips are inside vulva and detach fastening band	3
	No other steps had more than one participant unable to execute them	

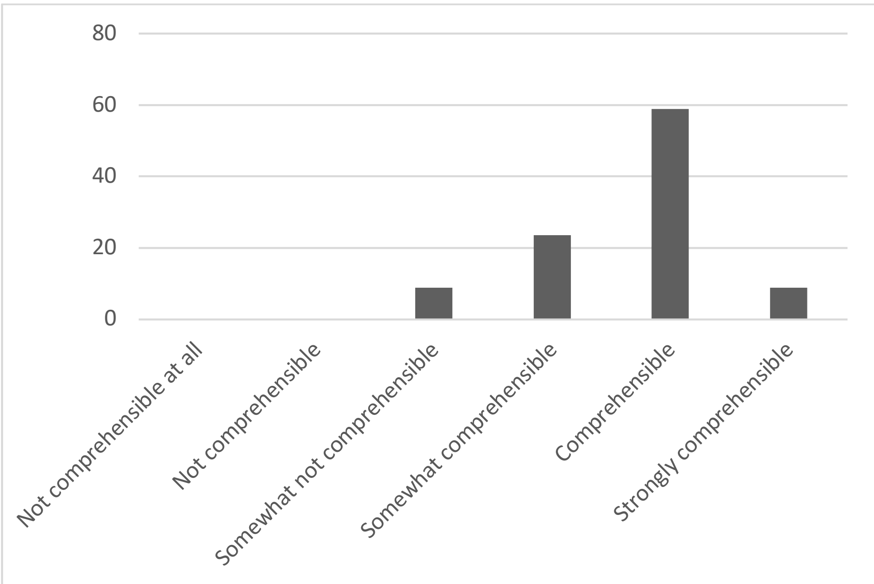
Step	Description
1	Unpack
2	Lubricate device
3	Lubricate birth canal
4	Slide fastening band
5	Insert cup
6	Check maternal tissue
7	Insert tip of device
8	Remove fastening band
9	Insert device
10	Stop at "0"
11	Confirm stop
12	Inflate cuff
13	Confirm inflation
14	Withdraw applicator
15	Re-inflate cuff
16	Pull
17	Confirm fetal descent
18	Deflate cuff
19	Detach cuff
20	Assist birth

6.3.7.2 Participant reported usefulness of IFU in performing simulated OVB with BD Odon Device

All participants (100%) felt that an IFU was necessary to perform a simulated OVB with the BD Odon Device. However, some participants were either not satisfied with the current IFU (30%) or did not feel that the current IFU was sufficient (25%).

Whilst all participants felt the current IFU was comprehensible, there was variation around the comprehensibility of some of the instructions (Figure 6-8).

Figure 6-8. Percentage of participants describing ease of understanding of IFU



6.3.7.3 Recollection of steps for performing OVB after exposure to IFU and training

The package of IFU and one-to one training appeared very successful at helping participants recall the 20 steps necessary to perform a simulated OVB using the BD Odon Device. Almost all users were able to correctly describe the majority of the steps (Figure 6-9). However, the steps required at the beginning of the procedure, were the steps that the least number of participants were able to recollect. This is also illustrated in Table 6-13. The initial steps of inserting the

Step	Description
1	Unpack
2	Lubricate device
3	Lubricate birth canal
4	Slide fastening band
5	Insert cup
6	Check maternal tissue
7	Insert tip of device
8	Remove fastening band
9	Insert device
10	Stop at "0"
11	Confirm stop
12	Inflate cuff
13	Confirm inflation
14	Withdraw applicator
15	Re-inflate cuff
16	Pull
17	Confirm fetal descent
18	Deflate cuff
19	Detach cuff
20	Assist birth

BD Odon Device are the most-novel and are unique to the BD Odon Device; it is therefore not surprising that these are the steps that participants had the most trouble achieving and recalling. Note that step 20 (deliver baby) was not assessed for recall as it was felt that it would be apparent in clinical practice that this would be required and is not dependent on the quality of the IFU.

Figure 6-9. Percentage of participants giving correct description of step

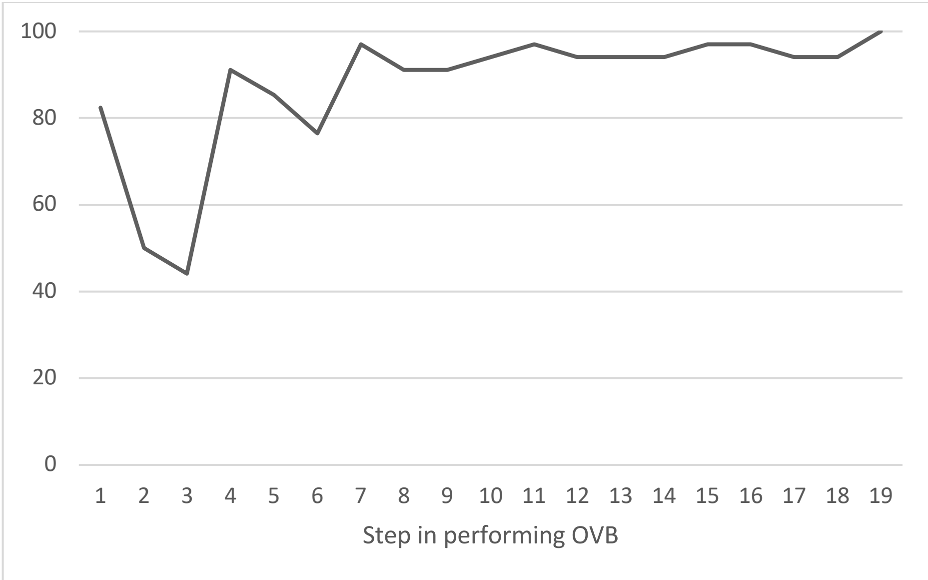


Table 6-13. Steps most likely to be incorrectly described by participants

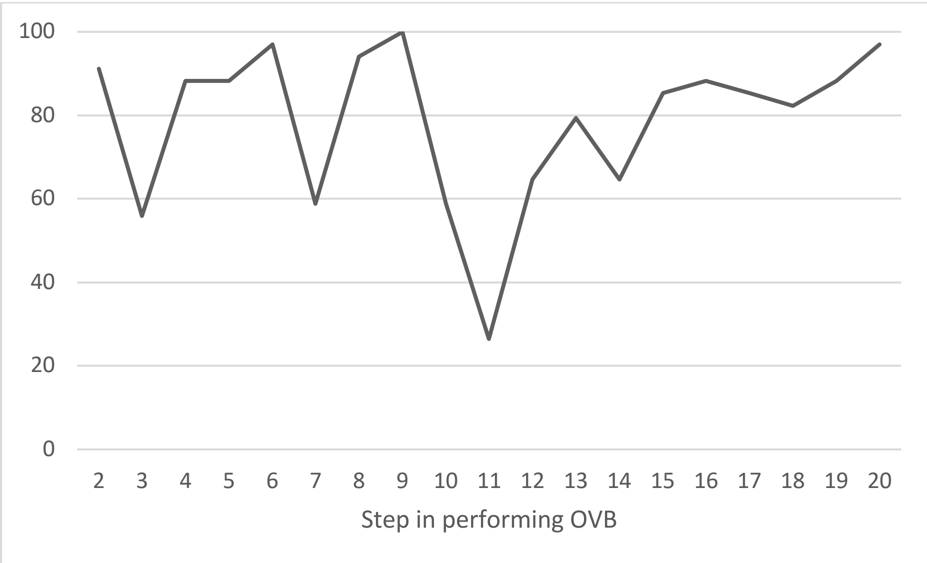
	Step(s)	Number of participants fail this step (n = 34)
Steps most likely to be incorrectly described		
	Ensure fastening band is in place	18
	Ensure spatula tips fully inserted	15
	Grip handle with viewing window uppermost	8

Step	Description
1	Unpack
2	Lubricate device
3	Lubricate birth canal
4	Slide fastening band
5	Insert cup
6	Check maternal tissue
7	Insert tip of device
8	Remove fastening band
9	Insert device
10	Stop at "0"
11	Confirm stop
12	Inflate cuff
13	Confirm inflation
14	Withdraw applicator
15	Re-inflate cuff
16	Pull
17	Confirm fetal descent
18	Deflate cuff
19	Detach cuff
20	Assist birth

6.3.7.4 Difficulty of individual steps

While Table 6-13 and Figure 6-9 describe the steps where participants are more likely to fail, they do not capture when steps were difficult or awkward to execute. Figure 6-10 and Table 6-14 demonstrate the difficulties that some participants experienced with each individual step. Of note, 26% of participants found the step of pushing the applicator up into the birth canal in a J-shaped curve and confirm that it is at '0' (step 11) to be 'easy' or 'very easy', and 32% of participants described this step as 'difficult'. There was also the previously noted difficulty with the earlier steps, such as orientation, ensuring the applicator was fully inside the sleeve, and removing the fastening band.

Figure 6-10. Percentage of participants describing steps as 'easy' or 'very easy'



Step	Description
1	Unpack
2	Lubricate device
3	Lubricate birth canal
4	Slide fastening band
5	Insert cup
6	Check maternal tissue
7	Insert tip of device
8	Remove fastening band
9	Insert device
10	Stop at "0"
11	Confirm stop
12	Inflate cuff
13	Confirm inflation
14	Withdraw applicator
15	Re-inflate cuff
16	Pull
17	Confirm fetal descent
18	Deflate cuff
19	Detach cuff
20	Assist birth

Table 6-14. Steps most likely to be described as "difficult" or "very difficult" by participants

	Step(s)	Number of participants describing this step(s) (n = 34)
Steps most likely to be described as "difficult" or "very difficult"		
	Pushing the applicator following the J-shaped curvature of the birth canal while monitoring progress in the viewing window	11 (32%)
	Ensure tips of the applicator are fully inserted	10 (29%)
	Push the applicator so the tips of the applicator are inside the vulva and remove fastening band	5 (15%)
	View "0" in the window as an indicator to stop pushing	5 (15%)

6.3.7.5 Device acceptability/intuitiveness

Most participants rate most aspects of the device as acceptable, comfortable or intuitive (Figure 6-11 and Table 6-15). However, participants struggled with removing the device from the packaging, 56% of participants did not find it easy to take the device out of the packet without compromising the integrity of the device, whilst 38% did not find it easy to take the device out of the packet without compromising the sterility of the device.

Figure 6-11. Percentage of participants describing part of device as "acceptable/intuitive" or "extremely acceptable/intuitive

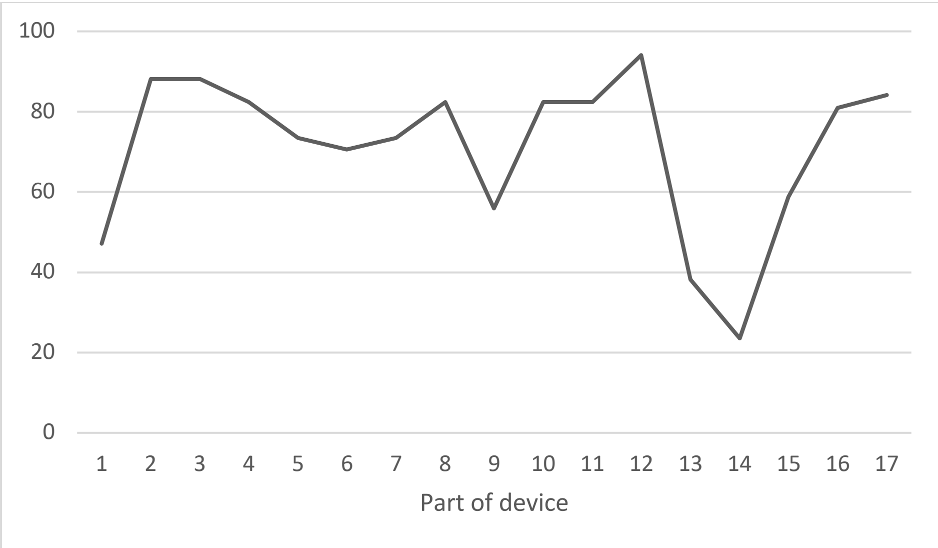


Table 6-15. Acceptability/intuitiveness of device

	Step(s)	Number of participants describing this step(s) (n = 34)
Aspects of device most likely to be described as "unacceptable/not intuitive" or "extremely unacceptable/not at all intuitive"		
	How easy is it to take the device out of the packet without compromising the integrity of the device?	19 (56%)
	How easy is it to take the device out of the packet without compromising the sterility of the device?	13 (38%)
	Are the sleeve and inserter handle orientation intuitive?	10 (29%)
	How acceptable is the overall packaging of the device?	10 (29%)

6.3.8 Conclusions

While most participants felt confident, comfortable, and were able to successfully demonstrate a simulated OVB using the BD Odon Device after exposure to the IFU and training, this human factors engineering analysis has however identified several areas where participants experienced difficulties in correctly using the device. The majority of these difficulties were associated with initial application of the device: ensuring the applicator was inserted into the sleeve, removing the fastening band and pushing the BD Odon Device up into the birth canal in a J-shaped curve were the most prominent recurring themes.

The device itself was mostly felt to be acceptable and intuitive, but several areas for improvement were highlighted. These were primarily concerning the removal of the device from the packaging, identification of the window that indicates when to stop pushing the device onto the head, and removal of the fastening band.

The IFU was felt to be essential by all participants, but significant minorities felt that the current iteration was not sufficiently detailed or satisfactory (24% and 30% respectively). However, the addition of a short (less than five minutes) one-to-one training practical training session appeared to be sufficient for most participants to correctly use (with confidence) the BD Odon Device. Alongside this training, a short training video may help provide sufficient training to ensure that all accoucheurs use the BD Odon Device correctly and safely. A summary of identified deficiencies and mitigations is shown in Table 6-16.

Table 6-16. Recurrent user difficulties and mitigations after Round 1 HFE testing (physical parts of device in italics)

	Recurring user difficulty	Mitigations
Device design	Device difficult to remove from packaging	Device rotated 180^0 in packaging IFU altered Training video produced
	Difficult for users to locate the *Viewing window*	*Viewing window* highlighted with a raised relief edge, IFU altered to highlight potential issue Training video produced
	During application of the device users were not easily able to monitor of the progression of the insertion	*'Limited' depth numeric scale indicator* replaced with a *continuous coloured numeric* scale counting down from 10 to zero, with zero signalling complete insertion Shortened *sleeve produced* IFU altered Training video produced
	When attempting to withdraw the *applicator* users grasped the *viewing window* as a leverage point rather than using the *handle* resulting in difficulties in withdrawal and user discomfort	Grip on the *handle* exaggerated *Viewing widow* given raised edge to reduce likelihood of users using the *viewing window* as grip feature IFU altered Training video produced
	Difficulty gripping *handle* during insertion/removal due to slipperiness of *handle*	Textured finish added to *handle* to increase friction
	Difficulties recalling how and when to deflate *air cuff* on crowning	*Deflation button* recoloured blue to highlight the button and colour-match to the *deflation line on the sleeve* as a reminder IFU altered Training video produced
IFU & training	Users unable to confirm adequate pump pressure	Greater emphasis on presence of pressure limiter on *bulb* in IFU Training video produced
	Variation in pressures generated by users after pumping the *inflation bulb*	Greater emphasis on slow, steady pumps in IFU, training video and face-to-face training
	Users were unable to consistently ensure the *sleeve* was not misaligned	Users informed they must confirm sleeve alignment prior to commencing OVB in IFU, training video and face-to-face training
	Users did not optimally position the *fastening band* prior to insertion	Greater emphasis on correct positioning and technique in IFU and training video IFU modified to highlight this feature
	Users found it difficult to remove the *fastening band* in an effective and timely manner	Greater emphasis on correct positioning and technique in IFU and training video IFU modified to highlight this feature

6.4 Formative round two (May 2016)

6.4.1 Summary

Following modifications to the training materials in response to the findings of during formative round one (Table 6-16) 11 naïve staff (seven midwives and four obstetricians) participated in formative round two. No changes have been made to the design of the device following formative round one. Formative round two was conducted using version two of the IFU (Appendix 2) and version two of the device (Figure 6-4). In addition, a three-minute video was created to outline the correct technique in the preparation, application and delivery of the baby using the BD Odon Device. After exposure to the IFU only, none of the five participants who were exposed to the IFU alone were able to successfully assist the birth of the fetal mannequin. However, when participants were able to watch the Training Video and were provided with a 10-minute one-to-one training session, all 11 participants were able to successfully deliver the fetal mannequin.

6.4.2 Objectives

Using HFE, the objectives of this study were:

- to identify any potential risks from how users interact with the BD Odon Device version two
- to evaluate the utility of the BD Odon Device version two, IFU version two and Training Video version one to inform any necessary changes and ensure that the device has an evidence-base

6.4.3 Primary outcomes

- To assess the extent to which users are able to demonstrate the correct technique in using the BD Odon Device v2 before and after exposure to IFU v2 and brief training including Training video v1

6.4.4 Secondary outcomes:

To identify:

- The impact of IFU v2, Training video v1 and face-to-face training on which steps within the procedure are most and least likely to contribute to the successful use of the BD Odon Device
- The usefulness and comprehensibility of IFU v2 and Training video v1 to users when performing an operative vaginal birth (OVB) using the BD Odon Device v2
- To what extent users can recall how to perform an OVB using the BD Odon Device after exposure to IFU v2 and Training video v1
- The acceptability of a shortened sleeve to users when performing an OVB using the BD Odon Device (additional outcome not assessed separately – the device used in these assessments was unchanged from Round One)

6.4.5 Methods

This was an observational HFE study.

Participants were selected from four groups of maternity staff representative of the future user population for the BD Odon Device.

These were:

- Obstetricians/gynaecologists
- Midwives
- Obstetricians/gynaecologists or midwives of 5 or more years continuous experience
- Obstetricians/gynaecologists or midwives of 4 or less years continuous experience

Eleven participants were recruited, satisfying guidance on the minimum required in each user group to achieve saturation of adverse events in FDA guidance on human factors studies (158).

Participants were again recruited from a single maternity unit in Bristol, UK. The Principal Investigator (SOB) approached participants by email and direct personal contact. Participants took part in the study outside of their employed hours. To compensate for their time participants were offered a £20 voucher for a department store, a level of compensation in line with guidance from the National Institute of Health Research (NIHR) (163).

All participants were asked to attempt a number of simulated delivery with the BD Odon Device on a maternal/fetal dyad (PROMPT Flex), with the baby in an OA position and station +2 spines.

Participants were asked to undertake their first attempted simulated OVB in the conditions above with either access to the IFU alone, or following access to the IFU and training. The steps required in this round to perform an OVB using the BD Odon Device were modified from Round 1, and are shown in Table 6-17.

Following this first attempted birth, participants were granted access to the IFU and full training (if not given already), and undertook a second attempted OVB. Following this, participants were fully trained again, and undertook a third attempted OVB. Participants were also questioned about how comfortable and intuitive they found the device, and were tested on how well they recalled the contents of the IFU. These procedures are laid out in the study flow chart (Figure 6-12).

Figure 6-12. Round 2 flow-chart

Part I

IFU task Assessment
(with IFU)

1. To assess the impact of the IFU in the task to ensure success of the procedure
2. To identify (IFU and non-IFU users) risks/recurring user patterns/errors that may influence future study design change sand IFU improvement

↓

Part II

IFU compliance/training (with IFU, video and training)

1. To understand user training needs in conjunction with IFU, video and trainer demonstration
2. To assess IFU compliance with regards to rates of success or deviations leading to risks or artifacts

↓

Part III

IFU content and comprehensibility (w/o IFU)

1. To assess the ability of the end user to understand the steps needed to perform application for a safe birth
2. To assess if the IFU content is perceived as sufficient by the user

↓

Part IV

Design assessment

1. To identify potential design changes to ensure the device can be used safely and efficiently
2. To assess device acceptability, comfort and confidence

Table 6-17. List of steps for performing an OVB with the BD Odon Device in Round 2

Step	Procedure
3	With the fastening band still intact, generously lubricate the inside and outside of the sleeve and the cup.
4	Lubricate birth canal
5	While holding the sleeve handle gently slide the fastening band to the top of the sleeve.
6a	Fold the cup and gently insert it into the vulva and check it has regained it's circular shape.
6b	Check that there is no maternal tissue trapped between the cup and the fetal head.
7	While gently pushing, continue inserting the sleeve and applicator into the vulva until the top of the fastening band is inside the vulva.
8	Open and remove the fastening band while the sleeve and applicator remains inside the vulva.
9	Between contractions, continue to gently insert the applicator, starting at 45º below the horizontal and following the curvature of the birth canal. Monitor progress by looking through the viewing window
10	Continue to insert the device and stop when "0" appears in the viewing window
11	Inflate the cuff by fully squeezing the bulb pump at least 8 times
12	While protecting the perineum with one hand, use the other hand to completely withdraw the applicator and cup, leaving only the sleeve in place
13	To compensate for possible reduction in cuff pressure after removing the applicator, squeeze the bulb pump 2 more times.
14	Grasp the sleeve handle, and during contractions pull gently and progressively following the J-shape of the birth canal
15	While continue to pull gently along the J-shape of the birth canal. Confirm the fetal head is descending with pulling efforts
16	Once you see the blue deflation line completely (approximately at crowning) deflate the cuff by pushing on the deflation button. Pull the sleeve handle continuing to press the deflation button following the J-shape of the birth canal
17	Continue to pull the sleeve handle while pressing the deflation button to pull the fetal head until the sleeve detaches from the head
18	Proceed to assist the birth of the baby as per normal procedure

6.4.6 Statistical analysis

Frequency data for outcomes is presented using descriptive statistics. No further inferential statistics were undertaken as this was a complete sample.

6.4.7 Results

Eleven participants undertook the study procedure. Demographics of study participants are described in Table 6-18.

Table 6-18. Participant demographic details

Characteristic		Results (n = 11)
Age		
	Mean	35.9
	Stan Dev	8.1
	Range	26 to 52
Gender		
	Male	0 (0%)
	Female	11 (100%)
Handedness		
	Right	10 (91%)
	Left	1 (9%)
Professions		
	Midwife	7 (64%)
	Obstetrician	4 (36%)
Years of experience		
	4 or less	6 (55%)
	≥5	5 (45%)
Number of operative vaginal births observed/performed per month		
	Mean	7
	Stan Dev	5.2
	Range	2 to 18
(If obstetrician)		

What is your instrument of choice?

(n = 4)

	Forceps	0 (0%)
	Ventouse	0 (0%)
	No preference	4 (100%)

The experience levels of participants in each study group are described in Table 6-19.

Table 6-19. Experience of participants by occupational group

	Experienced (n=5)	**Inexperienced (n=6)**
Midwife (n=7)	3	4
Obstetrician (n=4)	2	2

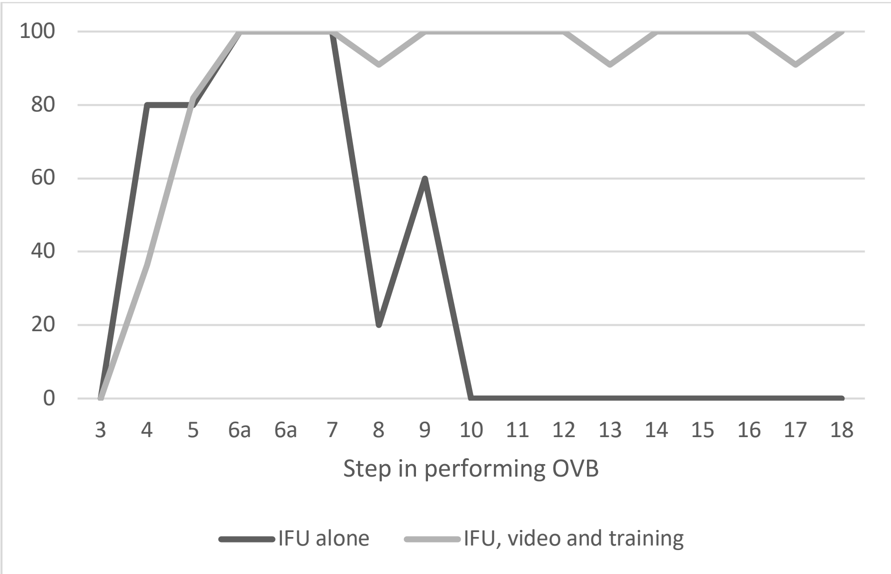
Step	Procedure
3	Lubricate device
4	Lubricate birth canal
5	Slide fastening band to top
6a	Fold & insert cup
6b	Check maternal tissue
7	Insert tip of device
8	Remove fastening band
9	Insert device
10	Stop at “0”
11	Inflate cuff
12	Withdraw applicator
13	Re-inflate cuff
14	Pull
15	Confirm fetal head descending
16	Deflate cuff
17	Detach cuff
18	Assist birth

6.4.8 Primary Outcomes

6.4.8.1 Successful performance of steps of an OVB using the BD Odon Device

Participants were significantly more likely to be able to successfully perform the steps of an OVB using the BD Odon Device after exposure to the IFU, face-to-face training and training video than after exposure to the IFU alone (Figure 6-13). Following exposure to IFU, training and training video all participants were able to successfully complete an OVB using the BD Odon Device once it had been inserted through the vulva (Step 7 in IFU v2). All steps are listed in Table 6-17.

Figure 6-13. Percentage of participants succeeding at performing each step of OVB procedure



Step	Procedure
3	Lubricate device
4	Lubricate birth canal
5	Slide fastening band to top
6a	Insert cup
6b	Check maternal tissue
7	Insert tip of device
8	Remove fastening band
9	Insert device
10	Stop at "0"
11	Inflate cuff
12	Withdraw applicator
13	Re-inflate cuff
14	Pull
15	Confirm fetal head descending
16	Deflate cuff
17	Detach cuff
18	Assist birth

6.4.9 Secondary outcomes

6.4.9.1 Steps of procedure most likely to succeed or fail by training level

The specific steps that participants were most likely to succeed or fail at for each training group are described in Table 6-20 and Table 6-21.

Table 6-20. Success/failure for participants IFU only

	Step(s)	Number of participants n=5
Steps most likely to be successful	Fold the cup and gently insert it into the vulva and check it has regained its circular shape	5
	Check that there is no maternal tissue trapped between the cup and the fetal head	5
	While gently pushing, continue inserting the sleeve and applicator into the vulva until the top of the fastening band is inside the vulva	5
Steps most likely to fail	All steps beyond Step 9: Between contractions, continue to gently insert the applicator, starting at 45º below the horizontal and following the curvature of the birth canal. Monitor progress by looking through the viewing window	5

Step	Procedure
3	Lubricate device
4	Lubricate birth canal
5	Slide fastening band to top
6a	Insert cup
6b	Check maternal tissue
7	Insert tip of device
8	Remove fastening band
9	Insert device
10	Stop at "0"
11	Inflate cuff
12	Withdraw applicator
13	Re-inflate cuff
14	Pull
15	Confirm fetal head descending
16	Deflate cuff
17	Detach cuff
18	Assist birth

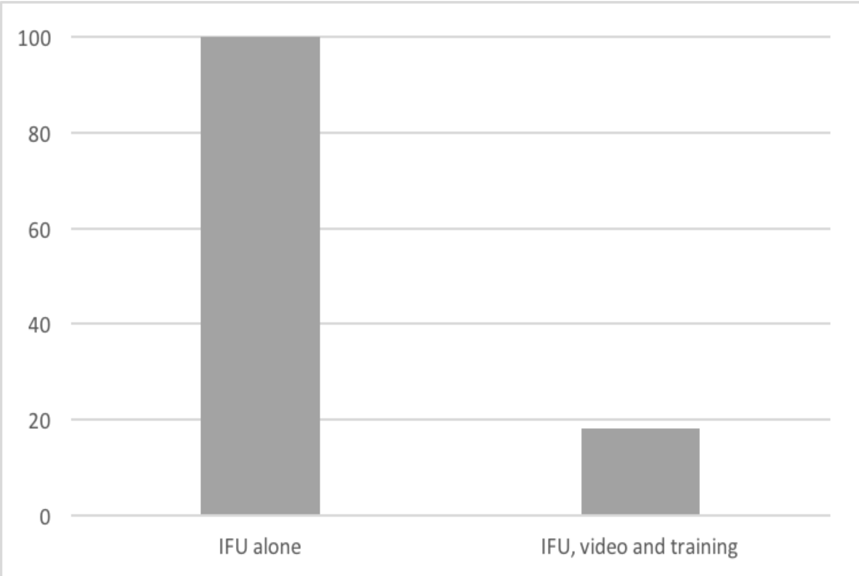
Table 6-21. Success/failure for participants following exposure to IFU, face-to-face training and training video

	Step(s)	**Number of participants succeed/fail at this step n = 11**
Steps most likely to be successful	Steps 6a, 6b, 7, 9, 10, 11, 12, 14, 15, 16 & 18	11
Steps most likely to fail	With the fastening band still intact, generously lubricate the inside and outside of the sleeve and the cup	7
	Lubricate birth canal	7
	Continue to pull the sleeve handle while pressing the deflation button to pull the fetal head until the sleeve detaches from the head	1

6.4.9.2 Encountering difficulty – before and after IFU, video and training

Participants encountered significantly fewer difficulties in using the BD Odon Device in simulated circumstances after exposure to the IFU, face-to-face training and training video compared to IFU alone (Figure 6-14). All participants reported difficulties with applying the device after exposure to the IFU alone, whereas only 2/11 (18%) did so following exposure to IFU, video and training.

Figure 6-14. Percentage of participants reported difficulties in using device after different levels of training.

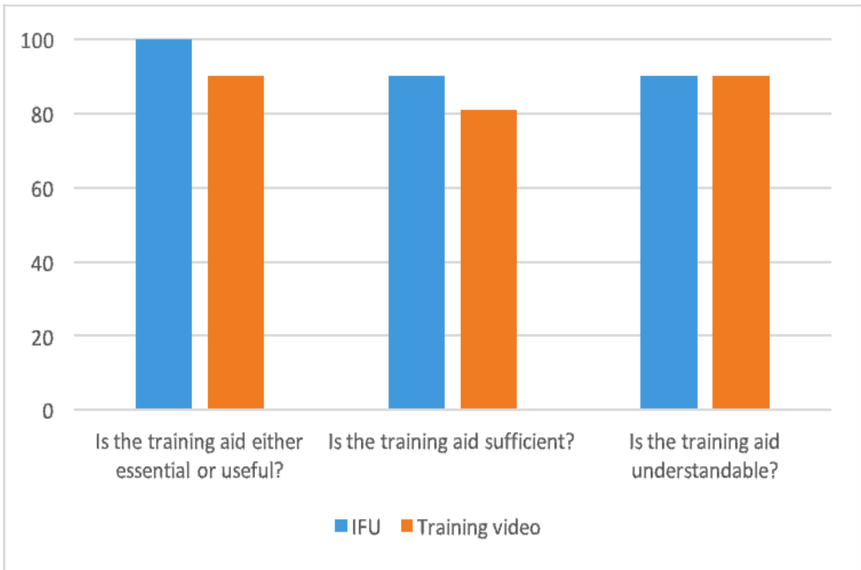


6.4.9.3 Participant reported usefulness, sufficiency and understandability of IFU and training video in performing simulated OVB with BD Odon Device

Almost all participants (100%) felt that both the IFU and training video were necessary to perform a simulated OVB with the BD Odon Device. However, some participants did not feel that the current IFU or training video were sufficient (10% and 20% respectively, Figure 6-15).

Interviews with these participants suggested that the dissatisfaction with the IFU could be resolved by simplifying the IFU, and the training video should be slower, with more detail paid to the initial steps in the procedure.

Figure 6-15. Percentage of participants who found training aids to be useful, sufficient and understandable



Step	Procedure
3	Lubricate device
4	Lubricate birth canal
5	Slide fastening band to top
6a	Insert cup
6b	Check maternal tissue
7	Insert tip of device
8	Remove fastening band
9	Insert device
10	Stop at “0”
11	Inflate cuff
12	Withdraw applicator
13	Re-inflate cuff
14	Pull
15	Confirm fetal head descending
16	Deflate cuff
17	Detach cuff
18	Assist birth

6.4.9.4 Recollection of steps for performing OVB after exposure to IFU and training

The package of IFU, video and one-to one training appeared very successful at helping participants recall the 17 steps necessary to perform a simulated OVB using the BD Odon Device. Almost all users were able to correctly describe the majority of the steps (Figure 6-16). However, the steps required at the beginning of the procedure were the steps that the least number of participants were able to recollect. This is also illustrated in Table 6-22. The initial steps of inserting the Odon device are the most-novel and are unique to the BD Odon Device; it is therefore not surprising that these are the steps that participants had the most trouble achieving and recalling.

Figure 6-16. Percentage of participants correctly describing steps of an OVB using BD Odon Device

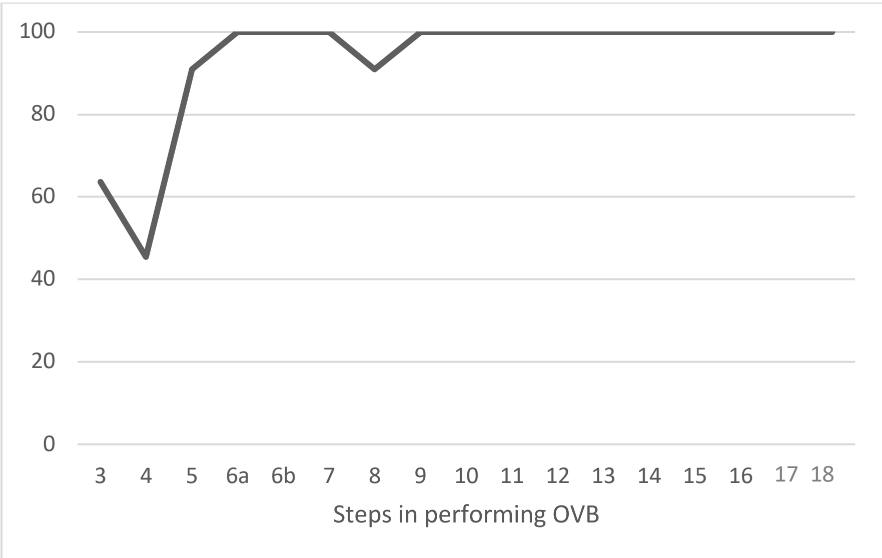


Table 6-22. Steps most likely to be incorrectly described by participants

	Step(s)	Number of participants incorrectly describe this step (n = 11)
Steps most likely to be incorrectly described	Lubricate birth canal	6
	With the fastening band still intact, generously lubricate the inside and outside of the sleeve and the cup	4
	While holding the sleeve handle gently slide the fastening band to the top of the sleeve	1

6.4.9.5 Comparison of short and long sleeve

One goal of this HFE was to examine whether participants preferred to use the BD Odon Device with a shorter sleeve.

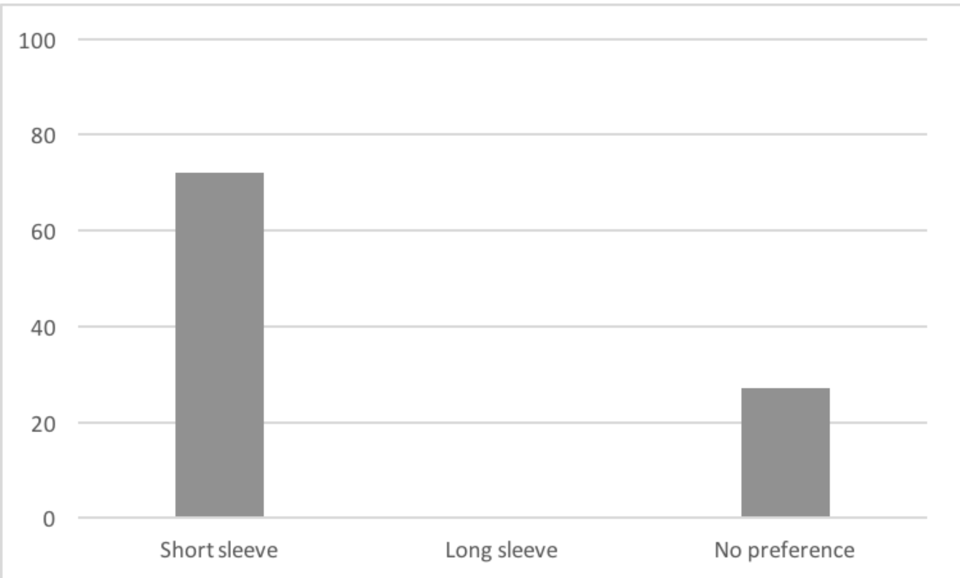
Participants were asked to undertake a simulated OVB using the shorter sleeve BD Odon Device after completing the formal HFE evaluations in this round.

Participants were asked whether they found the shorter sleeve to be usable, acceptable, and whether they had a preference for a shorter or longer sleeve. All participants (11/11, 100%) found the shorter sleeve to be usable and acceptable.

Participants either favoured the shorter sleeve or had no preference. No participants preferred the longer sleeve (Figure 6-17).

In interview responses, participants particularly mentioned the increased ability to see the viewing window with the shorter sleeve as a reason for this preference.

Figure 6-17. Percentage of participants expressing a preference for sleeve lengths



6.4.10 Conclusions

All participants were able to successfully demonstrate a simulated OVB using the BD Odon Device after exposure to the IFU, training video and face-to-face training.
This HFE analysis has however again demonstrated that, like the previous HFE analysis (round one) there are several areas where participants experienced difficulties in correctly using the device. These difficulties were associated with initial application of the device: particularly ensuring the applicator was inserted into the sleeve and removing the fastening band.

Both the IFU and training video were felt to be useful or essential by most participants, but some felt that the current iterations were not sufficient. Specifically, participants suggested the training video be made longer, more detailed, and go through the initial steps in greater detail. Suggestions concerning the IFU were conflicting – while some wanted the IFU to be simplified, while others wanted more detail.
A clear majority of participants favoured using a shorter sleeve – this appeared to be particularly helpful in allowing participants to identify the viewing window.
A list of recommendations and the subsequent changes made to the device and training materials is shown in Table 6-23.

Table 6-23. Recurrent user difficulties and mitigations after Round 2 HFE testing (physical parts of device in italics)

	Recurring user difficulty	Mitigations
Device design	Inflation of the *air chamber* was difficult as the *pumping bulb* was slippery dislodged from its housing	Fabric cover added to *pumping bulb* to increase friction *Pumping bulb* secured in position with fabric cover
	Difficult for users to locate the *Viewing window* as it was obscured by the sleeve	*Sleeve* shortened so as not to obscure the *Viewing window*
	Difficult to pull down the *fastening band* to lubricate the *sleeve* and then pull the *fastening band* back up prior to insertion	*Fastening band* re-designed to cover whole length of *applicator*
	Users struggled, or forgot, to remove the *fastening band*	Red *unfastening button* added to base of *fastening band*
IFU & training	Training video too fast	Training video remade at slower pace with longer pauses/segments
	Users unsure of names of device parts	Key device parts illustrated and labelled more prominently at beginning of IFU & training video
	Users did not keep the *deflation button* depressed when required	Greater emphasis on keeping the *deflation button* depressed in IFU & video

6.5 Formative round three (September 2016)

6.5.1 Summary

Prior to formative round three, modifications were made to the design of the device (those generated from both formative one and two, Table 6-16 and Table 6-23). For example, the grip on the *'Applicator'* was enhanced to enable greater traction during removal of the *'Applicator'*, and the *'Viewing Window'* (through which the operator can gauge how far the air cuff has travelled over the fetal head) was given a larger, relief border, to make it easier for the *'Viewing Window'* to be recognised by users. Minor modifications were also made to the training materials and IFU.

Eighteen naïve staff (eight midwives and ten obstetricians) participated in formative round three, which was conducted using versions three of the BD Odon Device and training video, and version three of the IFU.

Participants were more likely to be able to correctly use the BD Odon Device in all three stages (preparation, application and delivery) following exposure to the device and IFU alone compared to formative round one (78% during formative round three, compared to 25% in formative round one). Following exposure to all training materials, all participants (18) were able to complete more than 75% of steps correctly in all stages of an OVB using the BD Odon Device. All 18 participants who successfully applied the device were able to successfully deliver the fetal mannequin.

Following formative evaluation round three, minor changes were made to the device and training materials.

6.5.2 Alterations to device and training materials since round two HFE

Since the previous round of HFE, several changes have been made by the design team to the IFU, device, and training materials, incorporating both design and training material alterations suggested in round one and two.

IFU

- Amount of text reduced per step
- Steps re-numbered
- Greater emphasis placed on keeping deflation button depressed
- Key device arts illustrated and labelled more prominently

Device

- Fabric cover added to bulb to increase friction and facilitate easy pumping, also to secure position of pumping bulb (Figure 6-18 and Figure 6-19)
- Sleeve shortened so as not to obscure viewing window (Figure 6-20)
- Fastening band redesigned to cover whole length of applicator
- Red unfastening button added to base of fastening band

Figure 6-18. Assembled BD Odon Device v3

Figure 6-19. BD Odon Device v3 inserter

Figure 6-20. BD Odon Device v3 sleeve

Training materials

- Training Video developed with slower segments and more detailed captions

The purpose of this HFE study is to evaluate to what extent these modifications have enhanced the use of the device, and how they might be further improved.

6.5.3 Objectives

Using simulation, the objectives of this study were:

- to identify potential risks from how users interact with the BD Odon Device v3
- to evaluate the utility of IFU v3 (shown in Appendix 3) to inform any necessary changes and ensure that the product has an evidence-base

In clinical practice, all users will be exposed to the IFU and face-to-face training prior to using the BD Odon Device; therefore the performance of users following exposure to the IFU or Training Video alone has not been assessed.

6.5.4 Primary outcomes

- To assess the extent to which users are able to demonstrate the correct technique in using the BD Odon Device after exposure to IFU v3, Training Video v2 and face-to-face training

6.5.5 Secondary outcomes:

- To identify specific steps where users struggle to use the BD Odon Device v3 correctly to improve the performance and intuitiveness of the device
- To identify how IFU v3 might be improved further
- To identify how Training Video v2 might be improved further
- To determine how successfully users are able to recall the steps required to perform an OVB using the BD Odon Device from memory after exposure to IFU v3, Training Video v2 and face-to-face training

6.5.6 Methods

This was an observational HFE study.

Each participant was given the opportunity to have five attempts at conducting a vaginal birth using the BD Odon Device v3. Half of the participants were only exposed to the Training Video v2 when they used the device for the first time. They were then given the IFU v3 to read and brief one-to-one practical instruction prior to their second attempt. The other half of the participants were given the IFU v3 to read before their first attempt, followed by brief (less than 5 minutes) one-to-one practical instruction provided by an experienced obstetrician prior to their second attempt.

Prior to their final attempt, all participants had been exposed to the IFU v3, Training Video v2 and face-to-face training. These steps are shown in the study flow-chart (Figure 6-21).

Figure 6-21. Round 3 flow-chart

Part I

IFU task Assessment
(with IFU)

1. To assess the impact of the IFU in the task to ensure success of the procedure
2. To identify any recurring user patterns/errors that may lead to hazardous situations

↓

Part II

IFU compliance/training (with IFU, video and training)

1. To understand user training needs in conjunction with IFU, video and trainer demonstration
2. To understand further training requirements (if any) in conjunction with IFU, video and training

↓

Part III

IFU content and comprehensibility (w/o IFU)

1. To assess the ability of the end user to understand the steps needed to performe application for a safe birth
2. To assess if the IFU content is perceived as sufficient by the user

↓

Part IV

Design assessment

1. To evaluate that design modificaiton changes to the device have resulted in a device that can be used safely and efficiently
2. To assess device acceptability, comfort and confidence

The steps required to perform on OVB with the BD Odon Device v3 in this round of HFE are given in Table 6-24.

Table 6-24. List of steps for performing an OVB with the BD Odon Device in Round 3

Step	Procedure
3	Pull back the fastening band until the blue deflation line is exposed
4	With the fastening band still intact, generously lubricate the inside and outside of the sleeve and the cup
5	Lubricate birth canal
6	While holding the sleeve handle and applicator handle gently slide the fastening band to the top of the sleeve
7	Grip the applicator handle and ensure the viewing window is facing upwards
8a	Fold the cup and gently insert it through the vulva and check it has regained its circular shape
8b	Check that there is no maternal tissue trapped between the cup and the fetal head
9	With your hand on the handle of the applicator, gently push the device through the vulva. Use your other hand to guide the device and do not apply any force with it
10a	Unfasten the red button
10b	Open and remove the fastening band while ensuring that the sleeve and applicator remain in place inside the vulva
11	Between contractions, continue to gently insert the applicator, starting at 45° below the horizontal and following the curvature of the birth canal. Monitor progress by looking through the viewing window
12	Continue to insert the device and stop when “0” appears in the viewing window.
13	Inflate the cuff by fully squeezing the bulb pump at least 8 times
14	While protecting the perineum with one hand, use the other hand to completely withdraw the applicator and cup, leaving only the sleeve in place
15	To compensate for possible reduction in cuff pressure after removing the applicator, squeeze the bulb pump 2 more times
16	Grasp the sleeve handle, and during contractions pull gently and progressively following the J-shape of the birth canal
17	While continuing to pull gently along the J-shape of the birth canal. Confirm the fetal head is descending with pulling efforts
18	Once you see the blue deflation line completely (approximately at crowning) deflate the cuff by pushing on the deflation button. Pull the sleeve handle continuing to press the blue deflation button following the J-shape of the birth canal
19	Continue to pull the sleeve handle while pressing the blue deflation button to pull the fetal head until the sleeve detaches from the head
20	Proceed to assist the birth of the baby as per normal procedure

6.5.6.1 Sample

Participants were selected from four groups of maternity staff representative of the future user population for the BD Odon Device.

These were:

- Obstetricians/gynaecologists
- Midwives
- Obstetricians/gynaecologists or midwives of 5 or more years continuous experience
- Obstetricians/gynaecologists or midwives of 4 or less years continuous experience

Eighteen participants were recruited, satisfying guidance on the minimum required in each user group to achieve saturation of adverse events in FDA guidance on human factors studies (158).

Participants were recruited from a single maternity unit in Bristol, UK. The Principal Investigator (SOB) approached participants by email and direct personal contact. Participants took part in the study outside of their employed hours. To compensate for their time participants were offered a £20 voucher for a department store, a level of compensation in line with guidance from the National Institute of Health Research (NIHR) (163).

6.5.6.2 Statistical analysis

Frequency data for outcomes is presented using descriptive statistics. No further inferential statistics were undertaken as this was a complete sample.

6.5.7 Results

Eighteen participants undertook the study procedure. Demographics of study participants are described in Table 6-25.

Table 6-25. Participant demographic details

Characteristic		Results (n = 18)
Age		
	Mean	37.1
	Stan Dev	8.7
	Range	25 to 52
Gender		
	Male	1 (6%)
	Female	17 (94%)
Handedness		
	Right	16 (88%)
	Left	1 (6%)
Professions		
	Midwife	8 (44%)
	Obstetrician	10 (56%)
Years of experience		
	4 or less	4 (22%)
	>5	14 (78%)
Number of operative vaginal births observed/performed per month		
	Mean	11.6
	Stan Dev	7.5
	Range	2 to 30
(If obstetrician) What is your instrument of choice? (n = 10)		
	Forceps	4 (40%)
	Ventouse	4 (40%)
	No preference	2 (20%)

The experience levels of participants in each study group are described in Table 6-26.

Table 6-26. Experience of participants by occupational group

	Experienced (n=14)	**Inexperienced (n=4)**
Midwife (n=8)	5	3
Obstetrician (n=10)	9	1

Step	Procedure
3	Expose deflation line
4	Lubricate device
5	Lubricate birth canal
6	Return fastening band
7	Hold device upright
8a	Insert cup
8b	Check maternal tissue
9	Insert end of device
10a	Unfasten the red button
10b	Remove fastening band
11	Insert device
12	Stop at “0”
13	Inflate cuff
14	Withdraw applicator
15	Re-inflate cuff
16	Pull
17	Confirm descent of fetal head
18	Deflate cuff
19	Detach cuff
20	Assist birth

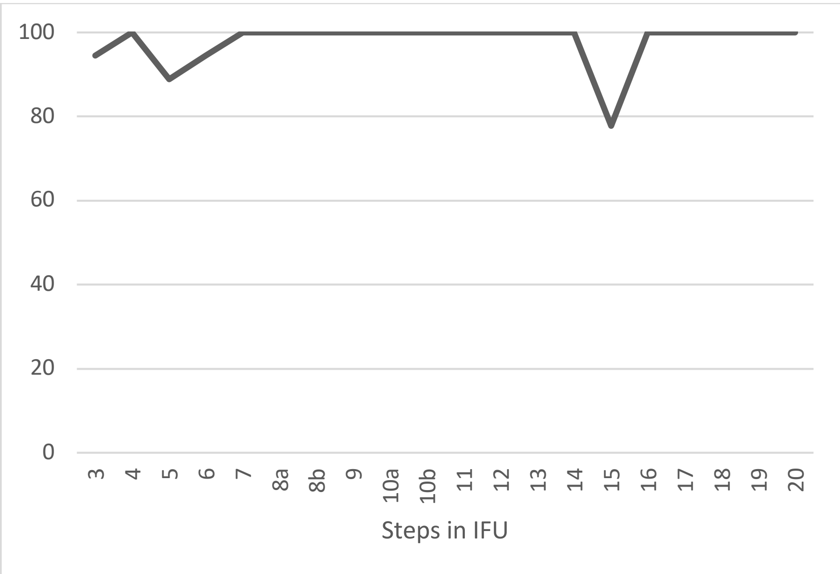
6.5.8 Primary Outcomes

6.5.8.1 Successful performance of steps of an OVB using the BD Odon Device

All participants were able to successfully complete a simulated OVB using the BD Odon Device after exposure to IFU v3, Training Video v2, and face-to-face training. All steps were performed successfully by more than 75% of users. Moreover, only one step was not successfully completed by more than one participant (step 15, re-inflation of the cuff after removal of the applicator). This high level of completion of steps is sufficient to allow the current training materials, with minor modifications, to be analysed in a formal validation study without further major alterations.

Participant success rates for each step of a simulated OVB are given in Figure 6-22.

Figure 6-22. Percentage of participants successfully performing each step of OVB after IFU, video and training



Step	Procedure
3	Expose deflation line
4	Lubricate device
5	Lubricate birth canal
6	Return fastening band
7	Hold device upright
8a	Insert cup
8b	Check maternal tissue
9	Insert end of device
10a	Unfasten the red button
10b	Remove fastening band
11	Insert device
12	Stop at "0"
13	Inflate cuff
14	Withdraw applicator
15	Re-inflate cuff
16	Pull
17	Confirm descent of fetal head
18	Deflate cuff
19	Detach cuff
20	Assist birth

6.5.9 Secondary outcomes

6.5.9.1 Steps where users fail to use to BD Odon Device correctly

In only one step did more than one user fail to use the BD Odon Device correctly (step 15, re-inflation of the air cuff following removal of the applicator). This was not done by 3 (17%) of participants. These errors occurred due to user oversight (forgetting to re-inflate) rather than difficulty in physically performing the step. This is shown by the recorded comment of the observer during this step; "Did not do pumps". Failure to perform this step will not generate harm to the mother or baby, but may reduce the clinical effectiveness of the BD Odon Device due to resulting in a lower cuff pressure.
To reduce the risk of the step not being completed, the step will be highlighted further within the Training Video and face-to-face raining.

No other steps were not successfully completed by more than one participant and as such do not require further alteration.

6.5.9.2 Participant reported sufficiency of IFU v3 in performing simulated OVB with BD Odon Device

Seventeen of eighteen participants (95%) agreed that IFU v3 is sufficient to provide birth practitioners with a satisfactory level of knowledge of the steps required to perform an OVB using the BD Odon Device. Interviews with participants suggested that the IFU could be improved by;

- Reducing the number of words used
- Highlighting the location of the deflation button
- Highlighting the importance of lubricating the inside surface of the sleeve

6.5.9.3 Participant reported sufficiency of Training Video v2 in performing simulated OVB with BD Odon Device

Sixteen of eighteen participants (89%) agreed that Training Video v2 is sufficient to provide birth practitioners with a satisfactory level of knowledge of the steps required to perform an OVB using the BD Odon Device.
Interviews with participants suggested that the Training Video could be improved by;

Step	Procedure
3	Expose deflation line
4	Lubricate device
5	Lubricate birth canal
6	Return fastening band
7	Hold device upright
8a	Insert cup
8b	Check maternal tissue
9	Insert end of device
10a	Unfasten the red button
10b	Remove fastening band
11	Insert device
12	Stop at "0"
13	Inflate cuff
14	Withdraw applicator
15	Re-inflate cuff
16	Pull
17	Confirm descent of fetal head
18	Deflate cuff
19	Detach cuff
20	Assist birth

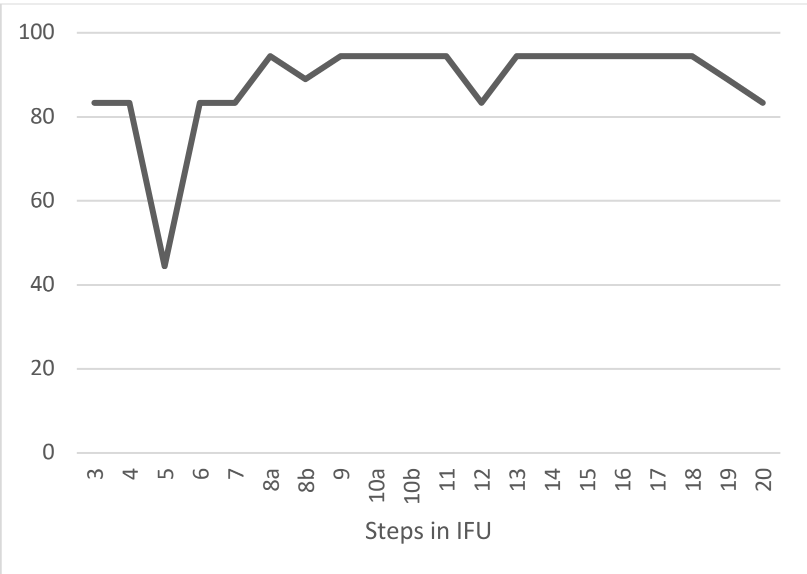
- Highlighting the individual steps using bullet points within the video
- Explain how the device works in different fetal positions

Recall of steps required to perform an OVB using the BD Odon Device

Participants were able to correctly recall 88% of steps required to perform an OVB using the BD Odon Device following exposure to IFU v3, Training Video v2 and face-to-face training. The successful recall rate per step is given in Figure 6-23. The level of successful recall demonstrated most often by participants for any step (the mode) was 95%; most commonly all participants except one could successfully recall any given step.

Participants has most difficulty recalling the steps at the beginning of the procedure. The step most often not recalled correctly was step 5 (lubricate birth canal, 44% successful recall rate). Given the marked differences between the preparation of the BD Odon Device and preparation of current obstetrical instruments (ventouse and forceps) prior to use, it is to be expected that participants will have more learning needs surrounding these unfamiliar steps compared to the more familiar steps later in the procedure, such as traction and delivering the fetal head.

Figure 6-23. Percentage of participants successfully recalling steps of OVB after exposure to IFU v3, Training Video v2 and face-to-face training



Conclusions

All participants were able to successfully perform a simulated OVB using the BD Odon Device after exposure to IFU v3, Training Video v2 and face-to-face training.

This HFE analysis has demonstrated that a minority of users may fail to correctly recall the initial steps required to use the BD Odon Device. However, given that all participants were able to successfully perform an OVB using the BD Odon Device, this deficit is not expected to significantly reduce the likelihood that the BD Odon Device can be correctly used in clinical practice.

Both the IFU and Training Video were felt to be sufficient by almost all participants. Participants did suggest areas where both could be improved. Specifically, participants suggested the Training Video include more information regarding the position of the baby and highlight each step individually. Participants suggested that the IFU should contain fewer words and highlight the importance of the deflation button and of lubricating inside the sleeve of the device.

A list of recommendations and the subsequent changes made to the device and training materials is shown in Table 6-27.

Table 6-27. Recurrent user difficulties and mitigations after formative round 3 HFE testing (physical parts of device in italics)

	Recurring user difficulty	Mitigations
Device design	*Button* securing the *sleeve* to the *applicato*r dislodged during preparation	Button re-manufactured with greater fastening strength
IFU & training	Users would find it useful to have importance of lubricating inside of *sleeve* highlighted	Need to lubricate inside *sleeve* stressed in face-to-face training
	Users would find it useful to have location of *deflation button* highlighted	Location of *deflation button* highlighted in IFU
	Users would find it useful to have steps expressed as bullet points within training video	Captions in video enlarged

6.6 Human Factor Validation Testing (March 2017)

6.6.1 Summary

Following minor modifications to the device and training materials made after formative round three, a Human Factors Validation Test was undertaken. The purpose of the HFVT was to definitively demonstrate that the BD Odon Device and corresponding IFU and training can be used by accoucheurs without producing patterns of failures that could result in a negative impact to patients or harm to users. 36 naïve staff (18 obstetricians and 18 midwives) from 14 countries (UK, Ireland, Germany, Italy, Spain, Denmark, Nigeria, South Africa, Kenya, Egypt, Jordan, India, Nepal and Australia) participated in the HFVT. Following exposure to face-to-face training and the IFU, at their third assessed attempt, all participants were able to successfully complete more than 75% of all steps required for use of the device (Table 6-4). All participants were able to successfully deliver the fetal mannequin.

6.6.2 Aims and objectives

This Human Factor Validation testing aimed to validate the performance of the BD Odon Device v3 and Instructions for Use v4 (Appendix 4) to provide evidence to ensure that the device does not lead to failures and that the risk controls by design are effective. The Training Video was not assessed as the study team did not want it to be considered as a sufficient training tool if used independently of face-to-face training.

6.6.3 Primary objective

To validate that the BD Odon Device v3 and IFU v4 can be safely and efficiently used by all user groups.

6.6.4 Secondary objectives

6.6.4.1 Mitigation of previously identified risks

To demonstrate that risks and user errors identified in previous human factors evaluations have been eliminated or reduced to acceptable low levels.

1.1.1.1 IFU understanding

To validate that users are able to understand and use the BD Odon Device IFU

6.6.4.2 Exploratory objective

To determine the acceptability and usability of additional training tools training (video) is to the intended user population.

6.6.4.3 Design process validation

To validate that a pre-chosen list of criteria that demonstrate a successful design and IFU process development have been fulfilled in simulated use.

6.6.5 Methods

This was a multi-centre human factors validation test to support the validation of the BD Odon Device design and IFU to demonstrate the ability of the of the end user to use the device and IFU safely and effectively by a sample of the likely user population to perform a simulated operative vaginal birth.

Simulations took place in Southmead Hospital, Bristol, UK, the Assembly Rooms, Bath, UK, and The Cape Town International Convention Centre, Cape Town, South Africa between 28.02.2017 and 22.03.2017. Simulations conducted in the Cape Town International Convention Centre took place alongside the Royal College of Obstetricians and Gynaecologists World Congress 2017.

Participants were required to attempt at least three simulated operative vaginal births. For all simulations, the fetus was in an occipito-anterior position with the vertex 2 cm below the ischial spines.

Participants were asked to recall the steps of an OVB performed using the BD Odon Device, and were asked questions regarding the design of the BD Odon Device. In addition, a subset of participants was asked about the acceptability and usefulness of a supplementary training video. This process is illustrated in Figure 6-24.

Figure 6-24. Validation test flow-chart

PART I

Critical Task and Design Assessment

Critical Task Assessment:

1. To Assess if participant is successfully able to perform the simulated procedure as per the IFU and Super User Training
    a. Participants will perform 3 simulated procedures
    b. Observer will assess tasks and record any deviations (live)
    c. Observer will carry on a debrief to identified root cause of errors (if any)

Design Assessment:

2. To assess the design (and modifications) acceptability, conformability and usability of the device from the end user perspective.
    a. Participants will be asked a series of questions (Likert scale) to assess their acceptability of the device design.

↓

PART II

IFU Content and comprehensibility

1. To assess the content and comprehensibility of the IFU in which the end user will be able to demonstrate their understanding of the IFU
    a. Participants will be asked to answer open questions describing each step.
    b. Observer will assess and record answer

↓

PART III

Training Video Assessment (EXPLORATORY)

1. To understand potential “Support Training Tools’ needs and usability by assessing the ability of the participant to use the BD Odon device
2. To understand needs of the development of additional training tools if any.

The steps required to correctly perform a simulated OVB with the BD Odon Device v4 in this round are shown in Table 6-28.

Table 6-28. List of steps required to correctly perform an OVB with BD Odon Device in Round 4

Phase	Step	Description
Application	2	Open BD Odon Device packaging while maintaining sterility
	3	Pull back the fastening band until the blue deflation line is exposed
	4	With the fastening band still intact, generously lubricate the inside and outside of the sleeve and the cup
	5	While holding the sleeve handle gently slide the fastening band to the top of the sleeve
	6	Grip applicator handle and ensure viewing window is facing upwards
	7	Fold the cup and gently insert it into the vulva and check it has regained its circular shape
	8	Check that there is no maternal tissue trapped between the cup and the fetal head
	9	While gently pushing, continue inserting applicator into the vulva until the top of the fastening band is inside the vulva
	10	Unfasten the red button
	11	Open and remove the fastening band while the sleeve and applicator remains inside the vulva
	12	Between contractions, continue to gently insert the applicator, starting at 45º below the horizontal and following the curvature of the birth canal. Monitor progress by looking through the viewing window
	13	Continue to insert the device and stop when “0” appears in the viewing window
	14	Inflate the cuff by fully squeezing the bulb pump at least 8 times
	15	While protecting the perineum with one hand, use the other hand to completely withdraw the applicator and cup, leaving only the sleeve in place
	16	To compensate for possible reduction in cuff pressure after removing the applicator, squeeze the bulb pump 2 more times
Delivery	17	Grasp the sleeve handle, and during contractions pull gently and progressively following the J-shape of the birth canal
	18	While continue to pull gently along the J-shape of the birth canal. Confirm the fetal head is descending with pulling efforts
	19	Once you see the blue deflation line completely (approximately at crowning) deflate the cuff by pushing on the deflation button. Pull the sleeve handle continuing to press the deflation button following the J-shape of the birth canal
	20	Proceed to assist the birth of the baby as per normal procedure
	21	Discard the used sleeve and applicator as per local policy. Do not reuse

Participants were asked to attempt three OVBs using the BD Odon Device, in the set-up previously described.

The ability of the participant to perform each step was assessed by the study team and recorded as either “success”, “success with operational difficulty”, “close call”, “failure”, “assistance” or “not applicable”. If the participant performed a step to the standard of “failure”, “assistance” or “not applicable”, the participant was debriefed by the study team to elicit the underlying reason as the why the participant had performed the way they had. The response was then recorded as either “artifact”, “device error”, “user misunderstood”, “abnormal use” or “user forgot”.

6.6.5.1 Structure of Part 1

In Part 1 of the study, participants were asked to attempt three OVBs using the BD Odon Device. Each attempt had a number of pre-conditions:

Attempt 1: Prior to this, participants had to undergo formal, face-to-face training in using the BD Odon Device, including two formative, non-recorded attempts at an OVB. They could, but did not have to, read the IFU.

Attempt 2: Prior to this, participants had to read the IFU

Attempt 3: Prior to this, participants could, but did not have to, read the IFU.

During Part 1, the pressure that participants were able to generate in the air cuff of the BD Odon Device was determined using a non-invasive pressure meter.

6.6.5.2 Contents of Part 2

Participants were asked open-ended questions regarding the procedure to perform an OVB using the BD Odon Device (as listed in Table 6-28). Responses were initially categorized as “correct answer”, “incomplete answer”, “incorrect answer” or “no answer/don’t know”. Following this, if they participant provided an answer that was categorized as either “incomplete answer”, “incorrect answer” or “no answer/don’t know”, they were debriefed by the study team. Following this, they were then re-categorized as either being able to provide, after prompting, a correct answer or not, and whether or not they had thought the instructions were clear.

6.6.5.3 Contents of Part 3

Seventeen out of 36 participants who chose to continue in the study were then exposed to and asked about a training video. Answers concerned the videos usefulness and acceptability, as well as suggestions as to how the video could be improved.

6.6.6 Sample Size

Thirty-six participants were recruited, fulfilling the FDA requirements of sample size in human factors studies in medical devices (158). Participants were recruited from 13 countries, providing a representative sample of the intended user population (birth practitioners in high, mid and low-resource settings). A list of participants and their counties of origin is shown in Table 6-29.

Table 6-29 Countries of origin of participants

Country	Midwives	Obstetricians	Total
United Kingdom	11	3	14
Spain	1	3	4
Italy	1	2	3
Germany	1	1	2
India	0	2	2
Nigeria	0	2	2
South Africa	0	2	2
Australia	0	2	2
Ireland	1	0	1
Nepal	0	1	1
Denmark	0	1	1
Jordan	0	1	1
Kenya	0	1	1
Total			36

6.7 Results

6.7.1 Participant demographics

Participant demographics are shown in Table 6-30.

Table 6-30. Demographics of participants in summative human factors evaluation

Characteristic		Count (n=36)
Age		
	Mean	44.8
	Std Dev	9.9
	Range	32 to 69
Gender		
	Male	11 (30%)
	Female	25 (70%)
Handedness		
	Right	34 (95%)
	Left	2 (5%)
	Unknown	
Profession		
	Midwife	18 (50%)
	Obstetrician	18 (50%)
Years of experience		
	4 or less	3 (8%)
	>5	33 (92%)
Number of OVBs observed/performed per month		
	Mean	8.1
	Stan Dev	5.8
	Range	1 to 20
Instrument of choice (If obstetrician)		
	Forceps	7 (39%)
	Vacuum	8 (44%)
	No preference	3 (17%)

Step	Description
2	Open device
3	Pull fastening band
4	Lubricate
5	Return fastening band
6	Hold upright
7	Fold & insert cup
8	Check maternal tissue
9	Insert end of device
10	Unfasten the red button
11	Remove fastening band
12	Insert device
13	Stop at "0"
14	Inflate cuff
15	Withdraw applicator
16	Re-inflate cuff
17	Pull
18	Confirm descent
19	Deflate & detach cuff
20	Assist birth

6.7.2 Primary outcome – ability of participants to successfully perform an OVB using the BD Odon Device

Participants were asked to perform an OVB using the BD Odon Device in accordance with the study flowchart (Figure 6-24). In these practical assessments, steps 1 & 21 (assess the suitability of the patient & disposal of the device according to local policies) were not examined.

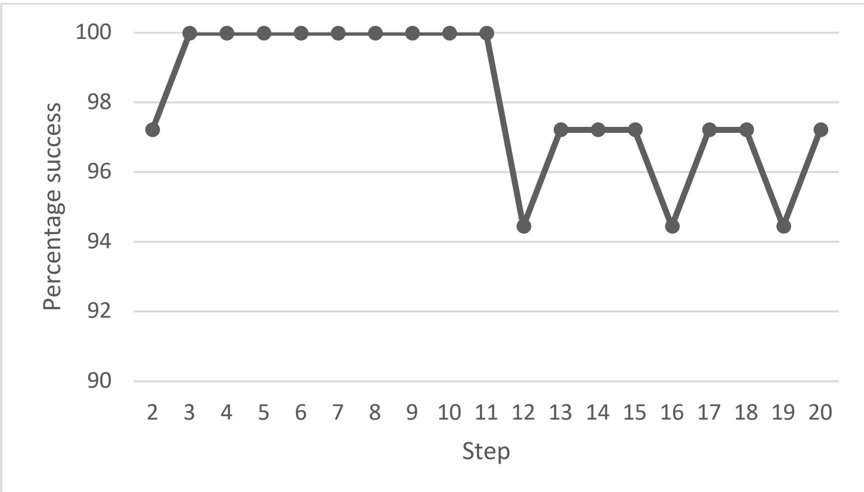
Results of participant success rates in attempts one, two and three are given in the following pages.

Step	Description
2	Open device
3	Pull fastening band
4	Lubricate
5	Return fastening band
6	Hold upright
7	Fold & insert cup
8	Check maternal tissue
9	Insert end of device
10	Unfasten the red button
11	Remove fastening band
12	Insert device
13	Stop at "0"
14	Inflate cuff
15	Withdraw applicator
16	Re-inflate cuff
17	Pull
18	Confirm descent
19	Deflate & detach cuff
20	Assist birth

6.7.2.1 Attempt One

Following attempt one, 35 of the 36 (97%) participants were able to successfully perform an OVB using the BD Odon Device. One participant was not able to complete the procedure (they could not proceed past step 12 – the participant neglected to insert the device at the correct angle, but did recall the correct step on direct questioning). Percentage success rate of completing each step for all participants are shown in Figure 6-25. All steps were completed successfully by a high proportion of participants. There were a number of isolated errors (for example step 12 was not completed successfully initially by two participants who were able to complete the procedure). However, on this occasion both participants spontaneously realized their error and the overlooked or miss-performed was performed correctly in subsequent attempts. This type of oversight is commonly observed during initial use of a new device and amended during subsequent use of the device. This occurrence is not considered to be a risk for the ability of the end user to use the device safely and effectively.

Figure 6-25. Percentage success of participants per step in first attempted OVB

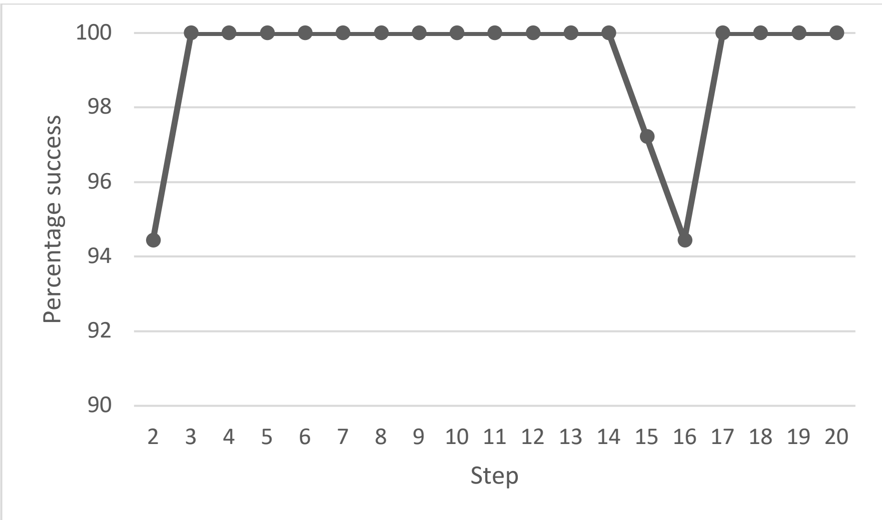


Step	Description
2	Open device
3	Pull fastening band
4	Lubricate
5	Return fastening band
6	Hold upright
7	Fold & insert cup
8	Check maternal tissue
9	Insert end of device
10	Unfasten the red button
11	Remove fastening band
12	Insert device
13	Stop at "0"
14	Inflate cuff
15	Withdraw applicator
16	Re-inflate cuff
17	Pull
18	Confirm descent
19	Deflate & detach cuff
20	Assist birth

6.7.2.2 Attempt Two

Following attempt two (prior to which all participants read the IFU), all participants were able to successfully complete a simulated OVB using the BD Odon Device. Percentage success rates for individual steps in the second round are shown in Figure 6-26. There were a number of isolated errors (for example step 16 was not completed successfully initially by three participants). However, all three participants realized their error when prompted and the miss-performed was performed correctly in subsequent attempts. This occurrence was independent from the ability of the participants to use the device, and is not considered to be a risk for the ability of the intended end user to use the device safely and effectively.

Figure 6-26. Percentage success of participants per step in second attempted OVB

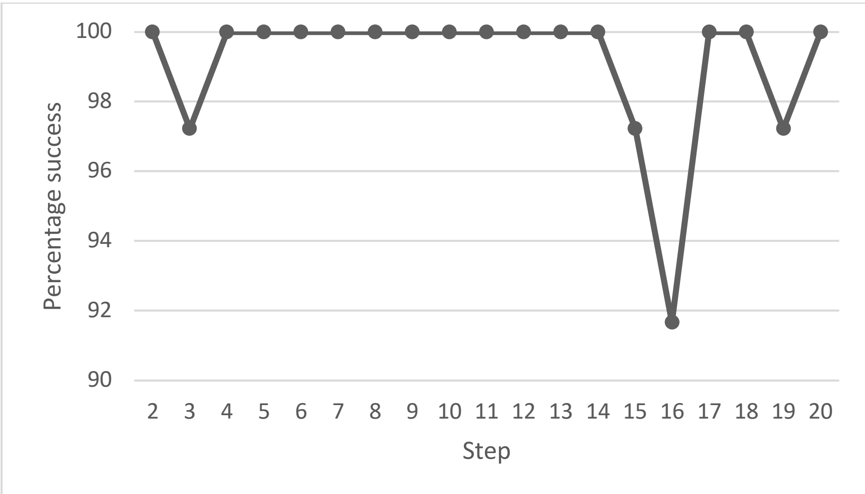


Step	Description
2	Open device
3	Pull fastening band
4	Lubricate
5	Return fastening band
6	Hold upright
7	Fold & insert cup
8	Check maternal tissue
9	Insert end of device
10	Unfasten the red button
11	Remove fastening band
12	Insert device
13	Stop at "0"
14	Inflate cuff
15	Withdraw applicator
16	Re-inflate cuff
17	Pull
18	Confirm descent
19	Deflate & detach cuff
20	Assist birth

6.7.2.3 Attempt Three

Following attempt three, all participants were again able to successfully perform an OVB using the BD Odon Device. Percentage success rates for individual steps in the third round, prior to de-briefing, are shown in Figure 6-27. There were a number of isolated errors (for example step 16 was not completed successfully initially by three participants). All participants who did not complete this step at their first attempt were aware of their error, were able to vocalize it when prompted and spontaneously self-corrected. This did not impair the completion of the whole task (birth of the baby). This occurrence was independent from the ability of the participant to use the device, and is not considered to be a risk for the ability of the intended end user to use the device safely and effectively.

Figure 6-27. Percentage success of participants per step in third attempted OVB

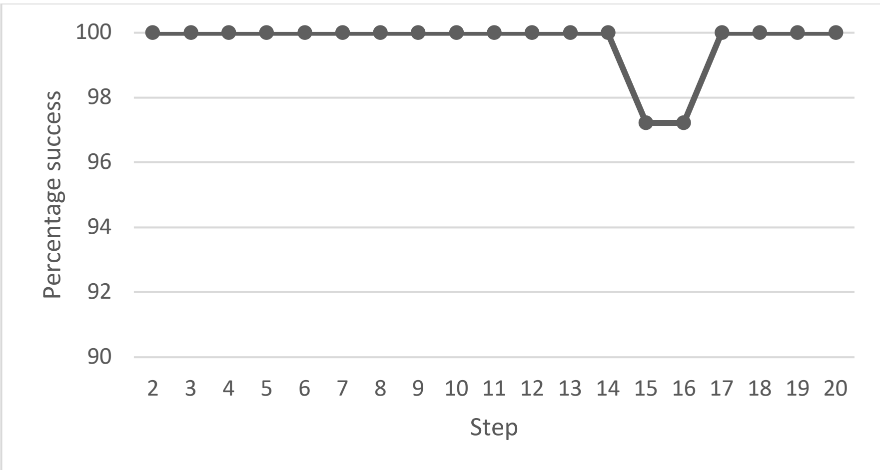


Step	Description
2	Open device
3	Pull fastening band
4	Lubricate
5	Return fastening band
6	Hold upright
7	Fold & insert cup
8	Check maternal tissue
9	Insert end of device
10	Unfasten the red button
11	Remove fastening band
12	Insert device
13	Stop at "0"
14	Inflate cuff
15	Withdraw applicator
16	Re-inflate cuff
17	Pull
18	Confirm descent
19	Deflate & detach cuff
20	Assist birth

6.7.2.4Attempt three following debriefing

Following their third attempt, participants who did not complete a step successfully were debriefed to explore why and determine a root cause. A step was considered to be able to be performed successfully by the participant if, after debriefing, the cause for the initial error was either an artifact, a device error, or a misunderstanding by the user. If any of these were present, the participant must have been able to spontaneously self-correct after an initial prompt without interruption to their ability to successfully perform the task. A step where the original error was determined to be due to either abnormal device use or a user forgetting the step was not considered to be successful. The rate of successful performance of each step, as determined following debriefing, is shown in Figure 6-28. In total, there were two errors which were not found to be artifact following debriefing. This gives an overall rate of success of 682 out of a total of 684 steps performed in the third attempted OVB (>99%).

Figure 6-28. Percentage success of participants per step in third attempted OVB following debriefing



Step	Description
2	Open device
3	Pull fastening band
4	Lubricate
5	Return fastening band
6	Hold upright
7	Fold & insert cup
8	Check maternal tissue
9	Insert end of device
10	Unfasten the red button
11	Remove fastening band
12	Insert device
13	Stop at "0"
14	Inflate cuff
15	Withdraw applicator
16	Re-inflate cuff
17	Pull
18	Confirm descent
19	Deflate & detach cuff
20	Assist birth

The individual participants and steps which were initially classed as an error, along with the root cause determined by the study team at debriefing, and the subsequent coding of the step are given in Table 6-31.

Table 6-31. Participant errors and root causes in attempt three

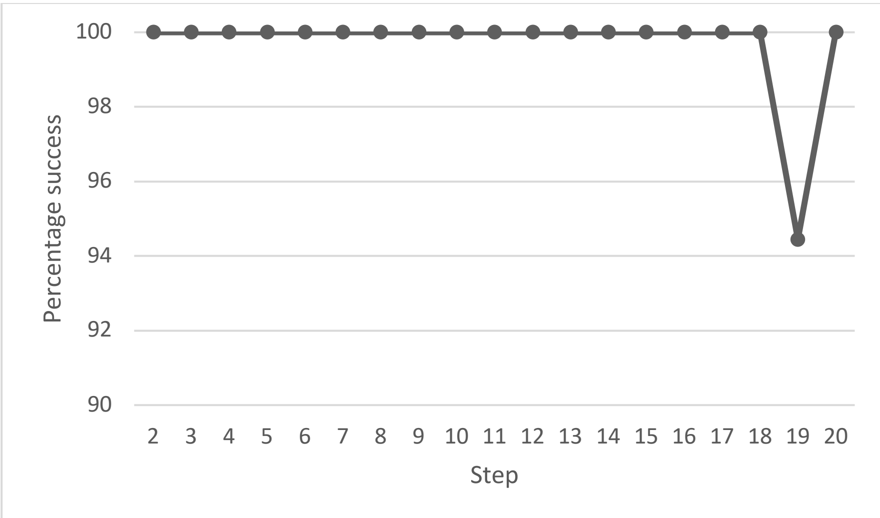
Step	Participant	Original performance	Root cause at debriefing	Subsequent determined cause	User determination of error source	Considered success?
3	8	Error	Opened the sleeve to lubricate but did not explain the process	Artifact	N/A	Yes
15	11	Error	Removed applicator prior to inflation of cuff – did not realise this was required	User forgot	Novelty of device	No
16	3	Error	Knew what to do when asked	Artifact	N/A	Yes
	9	Error	Remembered when prompted, but still forgot to complete task	User forgot	Novelty of device	No
	16	Error	Realised error when asked	Artifact	N/A	Yes

Step	Description
2	Open device
3	Pull fastening band
4	Lubricate
5	Return fastening band
6	Hold upright
7	Fold & insert cup
8	Check maternal tissue
9	Insert end of device
10	Unfasten the red button
11	Remove fastening band
12	Insert device
13	Stop at "0"
14	Inflate cuff
15	Withdraw applicator
16	Re-inflate cuff
17	Pull
18	Confirm descent
19	Deflate & detach cuff
20	Assist birth

6.7.2.5 Success rates of obstetricians only following debriefing at third attempt

The success rates of users by profession is given below. Obstetricians were all able to perform all steps successfully following debriefing (see Figure 6-29), with the exception of step 19 (one participant did not complete this successfully on their third attempt). However, this did not substantially impede the performance of the OVB and is not considered a risk for the ongoing safe and efficacious use of the device – failure to complete step 19 (detach the cuff) will not affect the ability of the user to deliver the baby, although it may increase the chance of a maternal perineal tear. A greater risk to the ability of the user to deliver the baby would be to deflate the cuff early (prior to birth).

Figure 6-29. Percentage success of obstetricians per step in third attempted OVB following debriefing

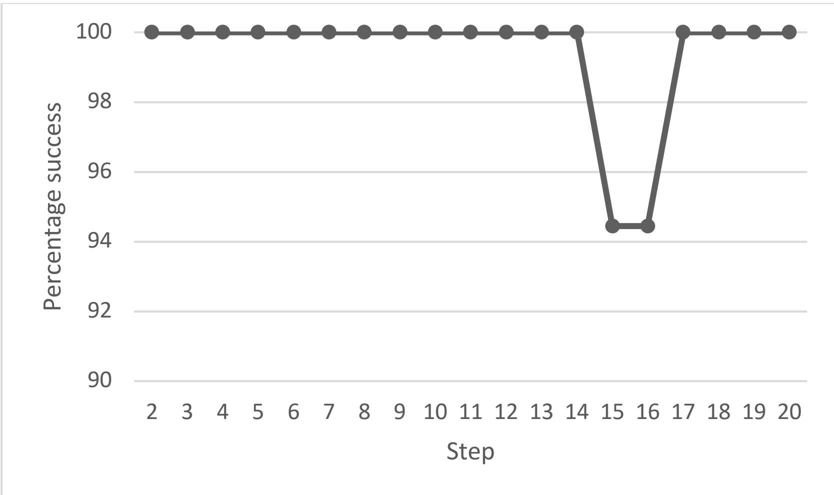


Step	Description
2	Open device
3	Pull fastening band
4	Lubricate
5	Return fastening band
6	Hold upright
7	Fold & insert cup
8	Check maternal tissue
9	Insert end of device
10	Unfasten the red button
11	Remove fastening band
12	Insert device
13	Stop at "0"
14	Inflate cuff
15	Withdraw applicator
16	Re-inflate cuff
17	Pull
18	Confirm descent
19	Deflate & detach cuff
20	Assist birth

6.7.2.6 Success rates of midwives only following debriefing at third attempt

Examined in isolation, all midwives correctly performed all steps of the OVB with the exception of two failures, at steps 15 and 16 (see Figure 6-30). Both of these errors (failure to re-inflate the cuff following withdrawal of the applicator and failure to withdraw the applicator would not substantially prevent a user from delivering a baby using the BD Odon Device. Of note, both participants self-corrected their error when prompted and assigned the cause of their error to the novelty of the device. Therefore neither error is considered a risk for the ongoing safe and efficacious use of the device.

Figure 6-30. Percentage success of midwives per step in third attempted OVB following debriefing



Success rates for both professional groups are given in tabular form in Table 6-32.

Step	Description
2	Open device
3	Pull fastening band
4	Lubricate
5	Return fastening band
6	Hold upright
7	Fold & insert cup
8	Check maternal tissue
9	Insert end of device
10	Unfasten the red button
11	Remove fastening band
12	Insert device
13	Stop at "0"
14	Inflate cuff
15	Withdraw applicator
16	Re-inflate cuff
17	Pull
18	Confirm descent
19	Deflate & detach cuff
20	Assist birth

Table 6-32. Correct responses per step on third attempt following debriefing

Step	Obstetricians Number of successes (%) (n = 18)	Midwives Number of successes (%) (n = 18)
2	18 (100%)	18 (100%)
3	18 (100%)	18 (100%)
4	18 (100%)	18 (100%)
5	18 (100%)	18 (100%)
6	18 (100%)	18 (100%)
7	18 (100%)	18 (100%)
8	18 (100%)	18 (100%)
9	18 (100%)	18 (100%)
10	18 (100%)	18 (100%)
11	18 (100%)	18 (100%)
12	18 (100%)	18 (100%)
13	18 (100%)	18 (100%)
14	18 (100%)	18 (100%)
15	18 (100%)	17 (94%)
16	18 (100%)	17 (94%)
17	18 (100%)	18 (100%)
18	18 (100%)	18 (100%)
19	17 (94%)	18 (100%)
20	18 (100%)	18 (100%)

Step	Description
2	Open device
3	Pull fastening band
4	Lubricate
5	Return fastening band
6	Hold upright
7	Fold & insert cup
8	Check maternal tissue
9	Insert end of device
10	Unfasten the red button
11	Remove fastening band
12	Insert device
13	Stop at "0"
14	Inflate cuff
15	Withdraw applicator
16	Re-inflate cuff
17	Pull
18	Confirm descent
19	Push button
20	Detach cuff
21	Assist birth
22	Dispose

6.7.2.7 Significance of different professional groups

The differing rates of success per step after debriefing of the professional groups was examined. Using students *t*-test with a two-tailed distribution and assuming paired samples, the chance that the difference between the two groups was not due to chance was 0.33. Therefore, the null hypothesis is not rejected and the statement that there is no significant difference in the performance of a simulated OVB using the BD Odon Device between midwives or obstetricians is supported.

6.7.3 Secondary objectives

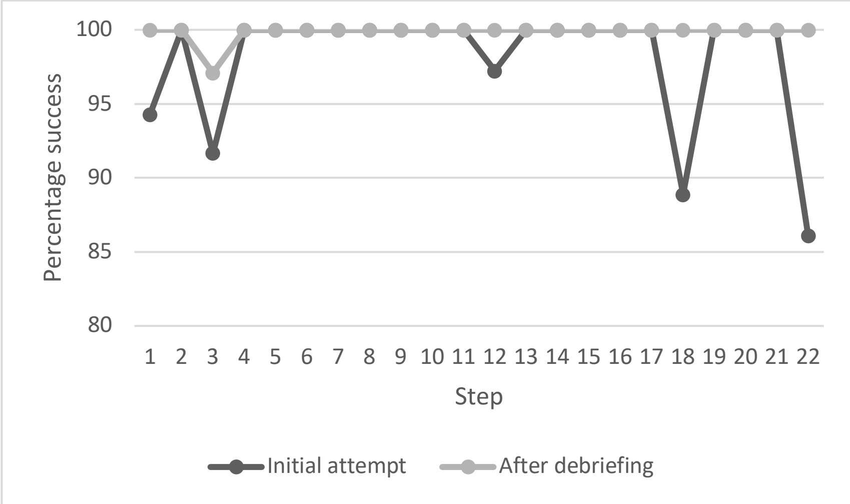
6.7.3.1 IFU understanding

In order to assess participant understanding of the IFU, participants were asked to describe the steps required to use the BD Odon Device to perform a simulated OVB. Thirty-five participants took part in this phase of the study. Participants were successful if they described accurately the steps required, in the correct order. If a participant provided an incomplete answer, they were given a non-directive verbal prompt by the assessor to expand on the point ("could you describe that in more detail"). Participants who either gave a complete answer initially, or after a verbal prompt, were classified as being successful at describing that step. Success rates of participants in correctly describing each step, both before and after debriefing, are given in Figure 6-31.

Note – to fully assess participant understanding, extra steps were included in this assessment. Step 1 (Asses the woman) was added. Step 19 ("Deflate cuff and continue to pull the sleeve handle") was split into two (Steps 19 & 20 in the side bar – "Push button" and "detach cuff"). Disposal of the device was also assessed (step 22 in the side bar). Therefore all charts in this section will list 22, rather than 19 steps.

Step	Description
2	Open device
3	Pull fastening band
4	Lubricate
5	Return fastening band
6	Hold upright
7	Fold & insert cup
8	Check maternal tissue
9	Insert end of device
10	Unfasten the red button
11	Remove fastening band
12	Insert device
13	Stop at "0"
14	Inflate cuff
15	Withdraw applicator
16	Re-inflate cuff
17	Pull
18	Confirm descent
19	Push button
20	Detach cuff
21	Assist birth
22	Dispose

Figure 6-31. Success rates of participants describing steps before and after debriefing



Following debriefing, the great majority of participants were able to successfully describe each step in order to perform an OVB using the BD Odon Device. There was one failure to successfully describe the step at step three. However, this would not have prevented the participant from successfully performing an OVB using the BD Odon Device, as the pulling of the fastening band is to facilitate the insertion of the sleeve, however, the sleeve can also be inserted if kept together without the fastening band. Moreover, the user realised their error. Therefore, this failure is not considered a risk in the safe and efficacious use of the BD Odon Device.

6.7.3.2 Sufficiency and satisfaction with IFU

Thirty-two out of 35 participants (92%) agreed that the IFU was both sufficient and satisfactory. Participants were asked how the IFU might be improved – these comments are given in Table 6-33.

Table 6-33. Attitudes of participants toward IFU and suggested improvements

Question	Yes	No	Comments by participant
Do you feel the current IFU is sufficient?	32	3	"You need to put somewhere not to pull the device out before pumping"; "you could add a better picture for showing a hand lubricating;"; "show perspective to the audience whereas it should be from the user"; "add that the initial push should be in the vulva"; "add a caption to 'firmly' push the applicator"
Are you satisfied with the IFU?	32	3	"Steps 11 and 12 can be a little unclear"; "could be done with simpler pictures and then writing"; "there's a lot, makes it seem more complicated"; "could be simpler - have 'quick steps' to go through"; "pictures bigger, writing bigger"

With the exception of a desire from some participants for the IFU to be simplified, there was no overall pattern of suggestions. The desire to simplify the IFU, although shared by the design team, is not considered to be practicable or compatible with the requirement to include enough information to enable safe use of the BD Odon Device. Moreover, all steps within the IFU were able to be recalled successfully by a large majority of participants (Figure 6-31).

6.7.4 Mitigation of previously identified risks

The mitigation of previously identified risks consisted of ensuring that patterns of miss-use of the BD Odon Device, observed in the prior formative rounds of HFE, were not observed in this summative study.

A list of patterns of miss-use observed in the most recent formative HFE study is given in Table 6-34, along with the subsequent mitigations to the device and IFU design.

Table 6-34. Recurrent user difficulties and mitigations after formative HFE testing

	Recurring user difficulty	Mitigations
Device design	Button securing the sleeve to the applicator dislodged during preparation	• Button re-manufactured with greater fastening strength
IFU & training	Users would find it useful to have importance of lubricating inside of sleeve highlighted	• Need to lubricate inside sleeve stressed in face-to-face training
	Users would find it useful to have location of deflation button highlighted	• Location of deflation button highlighted in IFU
	Users would find it useful to have steps expressed as bullet points within training video	• Captions in video enlarged

Following the summative study, no users reported spontaneous dislodging of the fastening button, nor did they express confusion as to its location. Similarly, no users expressed a desire for the need to lubricate inside the sleeve to be made more explicit. Therefore, all previously identified risks are deemed to have been mitigated to an acceptable level as to not impede the safe and effective use of the BD Odon Device, and further mitigation, although potentially possible, would not be practicable.

6.7.5 Exploratory Objective - To determine how useful and acceptable a training video is to the intended user population

A training video was developed alongside the face-to-face training and IFU. The future user population will be exposed to the face-to-face training and IFU prior to using the BD Odon Device. Completing the training and reading the IFU will be mandatory for practitioners to be able to use the BD Odon Device. However, alongside these compulsory training elements, some users expressed a desire for a training video. This was developed by the study team. Following attempted simulated OVBs and IFU content assessment, participants who were willing to continue in the study (17) were exposed to the training video. After this they were asked to perform a simulated OVB using the BD Odon Device, and were then asked about relevance and quality of the training video.

6.7.5.1 Performance of OVB after viewing the training video

After viewing the training video, all participants (n = 17) were able to correctly demonstrate all steps required to perform a simulated OVB using the BD Odon Device. There were no mistakes or errors.

Participants were then questioned as to how comprehensible they found the video. All participants found the video to be either “comprehensible” or “strongly comprehensible”. Participants were then asked a series of other questions exploring the video. While participants were generally positive, particularly of the ability of the video to show the precise mechanism of the device, they did suggest several alterations which may make the video more effective in the future. Specifically, participants highlighted the need to stress how many times the practitioner may apply traction on the device before abandoning the procedure. This will be included in future versions of the video. All questions asked, along with the responses, are given in Table 6-35.

Table 6-35. Attitudes of participants toward training video

Question	Yes	No	Comments by participant
Is this training video useful to be able to use the product?	17	0	Prefers training and IFU and video as a complement
Do you feel the current training video provides you with enough information about the usability of the device?	16	1	Just complementary in conjunction with IFU and training
Is the current training video is providing you with the same information as the IFU and Training?	17	0	"easier than IFU"; in the IFU it does not clearly explain that the numbers are going to go 9 to 0, but it became clear during the training; "use computer-based animations"; "explains the position of the device"; "shows you how the device is actually working inside so it would be best to show the video 1st and then training"
Would you suggest any further changes to improve the training video?	8	8	"could be clearer at explaining how to deflate in a rapid way and how much traction to apply with pulling"; "here we have a thing which is the best of the forceps and the best of the vacuum"; "could add how many times we can pull if baby is not coming down – perhaps 2 or 3 times?"; "explains position of device"; "correct, professional and clear"; "add the number of attempts that is ok to pull without descent"

Notwithstanding the suggestions by participants regarding how to improve the training video, the universal success of participants to perform an OVB using the BD Odon Device following exposure to the training video suggests that the video does not decrease understanding or performance and may be a useful adjunct to training future users in how to use the BD Odon Device safely.

6.7.6 Discussion

6.7.6.1 Primary outcome

Following face-to-face training and exposure to the IFU and following debriefing, obstetricians and midwives performed 99% of steps correctly (682 out of 684 individual steps).

The two steps that two participants performed incorrectly (steps 15 and 16, removal of applicator prior to re-inflation of cuff, and failure to re-inflate cuff prior to applying traction) were not repeated by any other participants, and were not felt by the participants in question to be due to a design or IFU fault, but rather due to the novelty of the device and application method. Therefore there does not appear to be an established pattern of misuse.

There was no significant difference in the rate of success between the two participant groups (midwives and obstetricians).

6.7.7 Secondary objectives

6.7.7.1 Understanding of the IFU

Participants found the IFU to be understandable. This was demonstrated by all participants being able to recall the steps required to perform an OVB using the BD Odon Device, with the exception of one step by one participant (step three). This equates to a success rate of 99.9% (769 out of 770 steps). In addition, 32 out of 35 participants found the IFU to be sufficient and satisfactory.

6.7.7.2 Mitigation of previously identified risks

Risks identified in previous formative rounds of human factors evaluation were addressed in design changes to the IFU and device prior to this validation study (see Table 6-5). In this study, none of the previously identified patterns of misuse were identified. This supports the conclusion that all previously identified risks have been successfully mitigated to a level unlikely to pose a significant risk to the safe and effective operation for the BD Odon Device.

1.1.1.2 Exploratory outcome – utility of a training video

Following exposure to the training video, all participants were able to successfully perform an OVB using the BD Odon Device. This confirms that a training video, while not in itself sufficient, may be a useful adjunct to formal face-to-face training and exposure to the IFU.

Participants made a series of comments highlighting how the video can be improved – these will be actioned in any future production of the video.

6.7.8 Safety

No adverse events were observed during the study. During all 124 observed attempted simulated OVBs the BD Odon Device performed correctly, with no incidents of mechanical fault or device failure.

6.7.9 Conclusion

The main purpose of this Human Factors Validation Testing was to support the validation of the ability of the end user to use the BD Odon Device and corresponding IFU. Pre-determined tasks (as per the IFU) to successfully conduct an OVB as well as user acceptance on the usability of the device were evaluated. The data collected during this study indicates the ability of the end user to use the device and IFU safely and effectively (with high rates of success of participants being correctly able to perform a simulated OVB using the BD Odon Device (99%), and high levels of satisfaction with IFU).

Furthermore, exploratory data was collected to assess the usability and comprehensibility of a training video to the end user which indicated that such a training video may be a useful adjunct to current validated training in the use of the BD Odon Device.

In conclusion, the Human Factors study for the validation of the BD Odon Device and IFU demonstrated that the device and IFU can be used safely and efficiently. Based on the results, the BO Odon Device and IFU are deemed to be validated.

6.8 Discussion

This is the first published study of the use of Human Factors Evaluation to systematically evaluate and iteratively improve the design and training materials of a new obstetrical instrument to expedite vaginal birth. The findings highlight the value of formal human factors testing before a novel device is introduced into clinical practice. The observation of midwives and obstetricians using the device in a simulated setting revealed numerous potential user errors and difficulties that have now been mitigated through revision of both the device design and the associated training materials. All simulated births were observed by an Obstetrician, R&D Engineer, the device Inventor and an expert in Human Factors. This multi-professional approach ensured that when a problem was identified, a solution could be rapidly developed, implemented and evaluated.

When presented with version four of the BD Odon Device and the associated training materials, all accoucheurs were able to successfully deliver a fetal mannequin using the device in a safe and competent manner, compared to 25% of accoucheurs using version two of the device and training materials. This finding suggests that the version four of the BD Odon Device is more intuitive and the training materials are more accessible and understandable to accoucheurs; a significant improvement when compared to version two.

The observation of 390 simulated operative vaginal births using the BD Odon Device informed numerous improvements to the device design, and also provided an opportunity to modify the associated IFU and training materials after the identification of common user errors. The use of simulation for investigation, rather than training, has previously been successfully used in obstetrics and has been associated with reduction in neonatal injury - an observation of 450 simulated births complicated by shoulder dystocia highlighted common user errors and provided an evidence base for practical training (115). The subsequent implementation of evidence based shoulder dystocia training was associated with an elimination of permanent neonatal brachial plexus injury associated with shoulder dystocia in one unit (110). Many neonatal injuries associated with vacuum or forceps are linked to user error (64), and therefore it is vital to learn from user errors and adapt training to mitigate risks associated with misuse before the BD Odon Device is introduced into clinical practice.

Participants had most difficulty preparing and applying the device, and comparatively little difficulty in using the device to deliver the fetal head once the device had been applied. In the second and third round of testing all participants who successfully applied the device were able to successfully deliver the fetal head. It is perhaps not surprising that participants struggled with the initial stages as the preparation and application of the device requires a completely novel technique. However, once the BD Odon Device is applied, the technique required to achieve a vaginal birth has similarities to that used during births assisted with both forceps and vacuum. Indeed, delivering the fetal head using a BD Odon Device mimics the dynamics of a spontaneous vaginal birth, a concept that should be familiar to all accoucheurs. When training accoucheurs to use the BD Odon Device the relative novelty of the preparation and application stages must be considered.

We chose to recruit both midwives and obstetricians to the study. Whilst specifically UK midwives are not the initial intended end-users of the BD Odon Device (although midwives in other international settings where midwifery practice routinely includes OVB may be), UK midwives in this study (represented in formative rounds one, two and three) represent a cohort of accoucheurs who are clearly familiar with the dynamics of a spontaneous vaginal birth, but have never performed an instrumental birth. When launched into practice it is hoped the BD Odon Device will be used to reduce morbidity in settings where instrumental birth is not currently commonly performed (164). Accoucheurs working in this environment will be familiar with the dynamics of a spontaneous vaginal birth, but are likely to be relatively unfamiliar with instrumental births. The device will also provide an alternative instrument to obstetricians who frequently perform instrumental births using forceps and/or vacuum. As such the intended end-users of the BD Odon Device will have vastly different prior experience of instrumental birth; this may affect how users interact with, and use, the device. In an attempt to address this issue, we recruited midwives and obstetricians across a spectrum of clinical experience to participate in the study. It is encouraging, therefore, that following training there was no significant difference between

the performance of midwives and obstetricians, using either the initial or final version of the BD Odon Device, IFU and training materials (Table 6-5).
The techniques required to perform an operative vaginal birth using non-rotational forceps or vacuum are broadly standardised in internationally recognised national guidelines (Royal College of Obstetricians and Gynaecologists (12), American College of Obstetricians and Gynecologists (165), Royal Australian and New Zealand College of Obstetricians and Gynaecologists (137) and the Collège National des Gynécologues et Obstétriciens Français (138)) and we therefore do not anticipate that experienced users from different settings will interact with the device is a significantly different manner. This is in addition to the results of the Human Factors Validation Test within our study, which demonstrated similar levels of success across participants of 14 separate national backgrounds (Table 6-29). This suggests that there is a common degree of understanding of the process of normal and assisted birth amongst the intended future end-users of the BD Odon Device. This commonality of knowledge would potentially allow a desirable distributed model of training to be successful. Models such as this, where skills are taught by centrally-trained local faculty to local trainees, and which have previously been used to disseminate 'best-practice' strategies to deal with universal obstetric procedures, such as manoeuvres for shoulder dystocia, have been demonstrated to result in sustained knowledge acquisition (166), to be relatively low-cost (167), and to improve real-world outcomes in a variety of settings (93,110,168).

The adoption of the BD Odon Device into clinical practice necessitates the acquisition of a new skill by accoucheurs. This study has demonstrated that, with an appropriately designed device and simple training package, clinicians of all abilities are able to acquire and utilise the required skills efficiently and effectively. The challenge of introducing a novel medical device into obstetric practice should not be underestimated. However, the collaboration between clinicians, R&D engineers and human factor specialists has provided a rigorous evaluation and rapid cycles of iterative improvement of both the device and training package. The Human Factors Evaluations have not only aided in the development of the BD Odon Device and IFU, but have also ensured that the BD Odon Device is able to be used safely and intuitively as practicably possible prior to *in-vivo* testing.

Appendix 1 IFU v1

INSTRUCTIONS FOR USE (FOR SIMULATION ONLY NOT FOR USE IN PATIENTS)

1. Ensure conditions for safe application are met
   a. Full dilation of cervix, +2 station or below, ruptured membranes, cephalic vertex presentation (OA, OP, OT positions)
   b. Provide adequate analgesia according to facility procedures
   c. Place women in the laying up (lithotomy) position
   d. Empty bladder
   e. Re-check fetal position

2. Take BD Odon Device out of package without compromising the sterility of the device

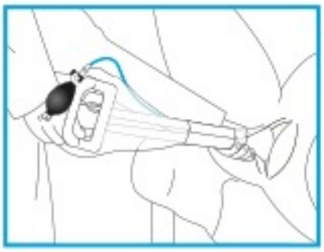
3. Ensure the tips of the spatula are fully inserted in the sleeve pockets and that the sleeve is undamaged

4. Ensure the fastening band is in place

5. Generously lubricate the outside and inside of the sleeve and the cup

6. Lubricate birth canal

7. Grip the applicator handle and ensure the viewing window is facing up

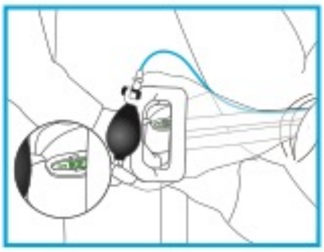


8. Fold the cup and gently insert it into the vulva

9. Check with one finger that there is no maternal tissue between the cup and the fetal head

10. When there is no contraction, gently push the applicator until the tip of the spatula is inside the vulva and then remove the fastening band.

11. Continue to gently push the applicator following the J-shaped curvature of the birth canal along a 30 degree angle and monitor progress through the viewing window.



12. Stop pushing once "0"appears in the viewing window.

13. Inflate the cuff by fully squeezing the bulb pump 6 times

A

INSTRUCTIONS FOR USE (FOR SIMULATION ONLY NOT FOR USE IN PATIENTS)

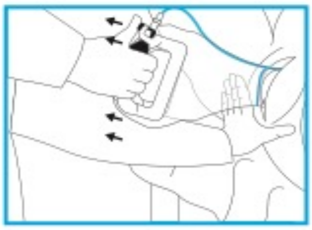
14. While protecting the perineum with one hand, withdraw the applicator with the other hand while leaving the sleeve in place.

15.Inflate the cuff by fully squeezing the bulb pump 2 times to compensate for reduction of pressure due to the withdrawal of the applicator

16. Grasp the sleeve handle, and during contractions pull gently and progressively along the J-shape of the birth canal

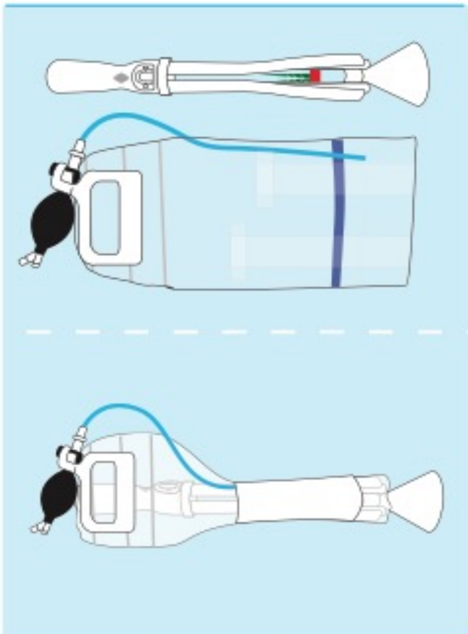
17. Confirm fetal head is descending with pulling efforts

18. Once you see the blue deflation line, confirm crowing of the fetal head and deflate the cuff by pushing the deflation button.



19. Continue to use the sleeve handle while pressing the deflation button to pull the fetal head until the sleeve detaches from the head.

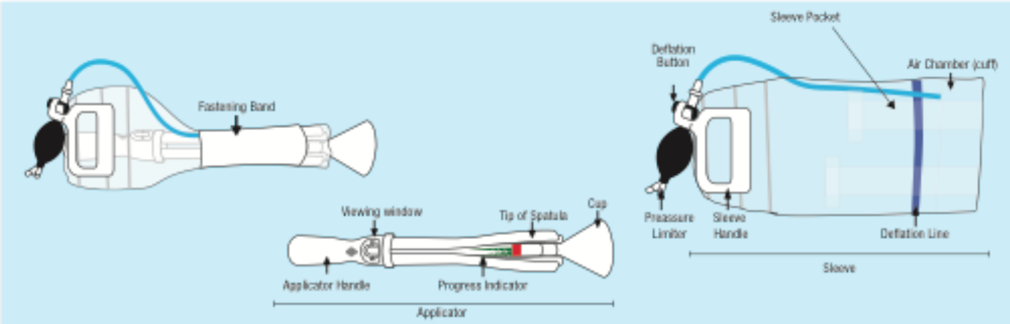
20. Deliver the baby as per normal procedure.



B

Appendix 2 IFU v2

INSTRUCTIONS FOR USE (FOR SIMULATION ONLY NOT FOR USE IN PATIENTS)



1. Ensure conditions for safe application of device are met:

   a. Full dilation of cervix, fetal head +2 station or below, cephalic vertex presentation (OA, OP, OT positions)

   b. Provide adequate analgesia according to facility procedures

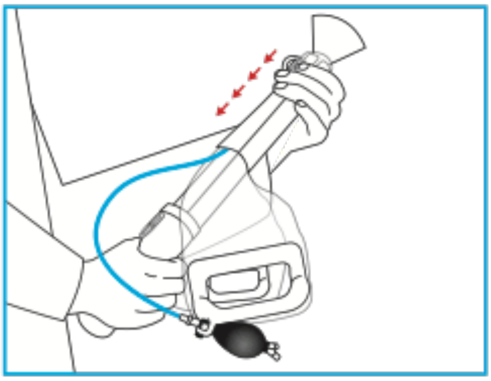
   c. Position women in lithotomy position

   d. Empty bladder

   e. Re-confirm fetal position

2. Remove BD Odon Device from packaging without compromising the sterility of the device.

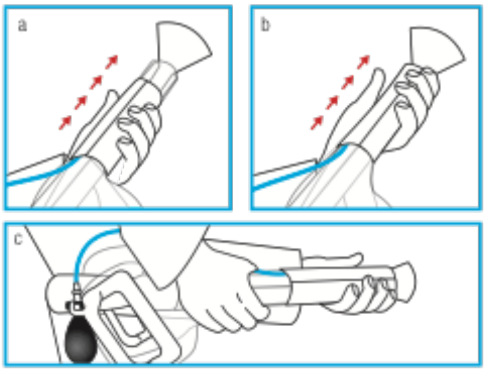
3. Ensure tip of applicator spatula are fully inserted in the sleeve pockets by holding the applicator with one hand whilst pulling down on the sleeve with the other hand.



4. With the fastening band still intact, generously lubricate the outside and inside of the sleeve and the cup.

5. Lubricate birth canal

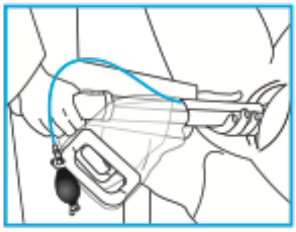
6. Hold the sleeve and applicator and gently slide the fastening band to the top of the sleeve.



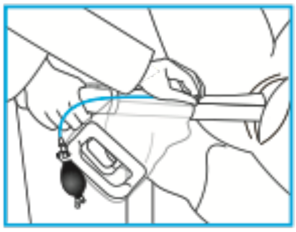
7. Fold the cup and gently insert it into the vulva.

8. Continue inserting the sleeve and applicator into the vulva until the top of the fastening band is inside the vulva.

Note: the numbers to monitor progress will start to appear after half of the device has been inserted.



9. Open and remove the fastening band while the sleeve and applicator remains inside the vulva.



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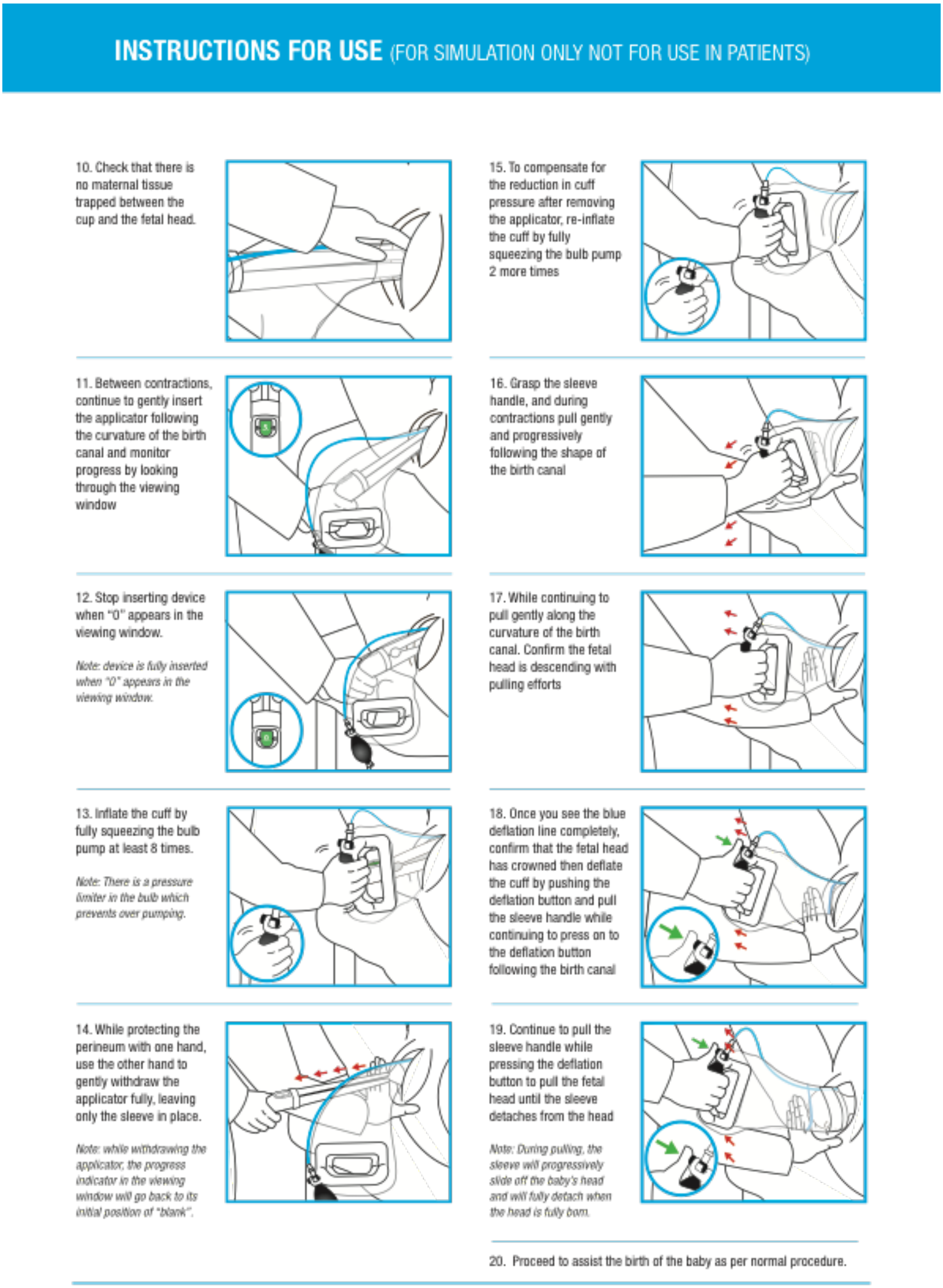


INSTRUCTIONS FOR USE (FOR SIMULATION ONLY NOT FOR USE IN PATIENTS)

10. Check that there is no maternal tissue trapped between the cup and the fetal head.

11. Between contractions, continue to gently insert the applicator following the curvature of the birth canal and monitor progress by looking through the viewing window

12. Stop inserting device when "0" appears in the viewing window.

Note: device is fully inserted when "0" appears in the viewing window.

13. Inflate the cuff by fully squeezing the bulb pump at least 8 times.

Note: There is a pressure limiter in the bulb which prevents over pumping.

14. While protecting the perineum with one hand, use the other hand to gently withdraw the applicator fully, leaving only the sleeve in place.

Note: while withdrawing the applicator, the progress indicator in the viewing window will go back to its initial position of "blank".

15. To compensate for the reduction in cuff pressure after removing the applicator, re-inflate the cuff by fully squeezing the bulb pump 2 more times

16. Grasp the sleeve handle, and during contractions pull gently and progressively following the shape of the birth canal

17. While continuing to pull gently along the curvature of the birth canal. Confirm the fetal head is descending with pulling efforts

18. Once you see the blue deflation line completely, confirm that the fetal head has crowned then deflate the cuff by pushing the deflation button and pull the sleeve handle while continuing to press on to the deflation button following the birth canal

19. Continue to pull the sleeve handle while pressing the deflation button to pull the fetal head until the sleeve detaches from the head

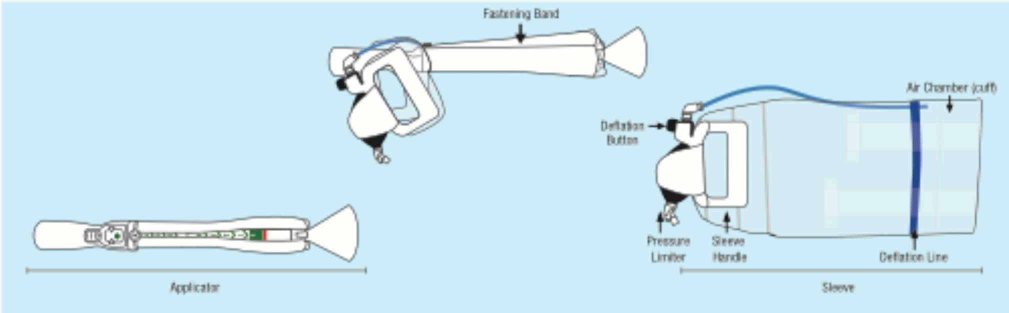
Note: During pulling, the sleeve will progressively slide off the baby's head and will fully detach when the head is fully born.

20. Proceed to assist the birth of the baby as per normal procedure.

B

Appendix 3 IFU v3

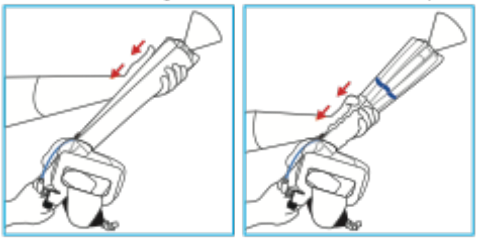
INSTRUCTIONS FOR USE (FOR SIMULATION ONLY NOT FOR USE IN PATIENTS)



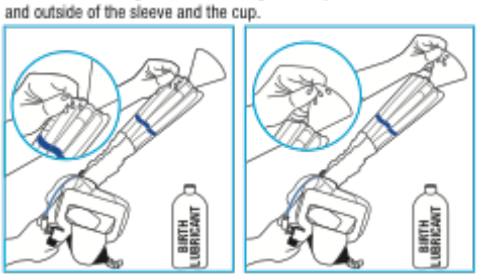
1. Ensure conditions for safe application of device are met:
   a. Full dilation of cervix, fetal head +2 station or below, cephalic vertex presentation (OA, OP, OT positions), rupture of membrane
   b. Provide adequate analgesia according to facility procedures
   c. Position women in lithotomy position
   d. Empty bladder
   e. Re-confirm fetal position

2. Remove BD Odon Device from packaging without compromising the sterility of the device.

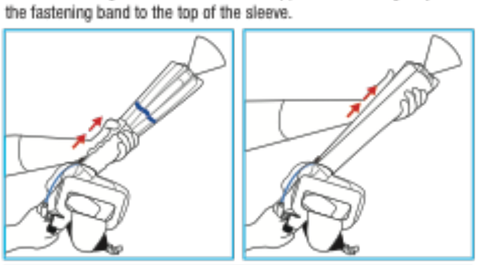
3. Pull back the fastening band until the blue deflation line is exposed.



4. With the fastening band still intact, generously lubricate the inside and outside of the sleeve and the cup.

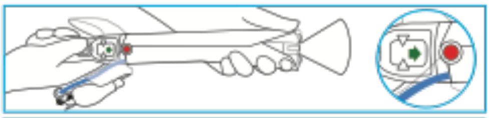


5. While holding the sleeve handle and applicator handle gently slide the fastening band to the top of the sleeve.



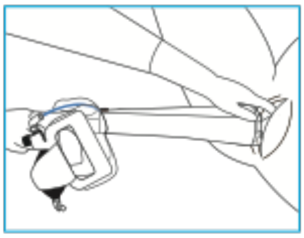
6. Lubricate birth canal.

7. Grip the applicator handle and ensure the viewing window is facing upwards.

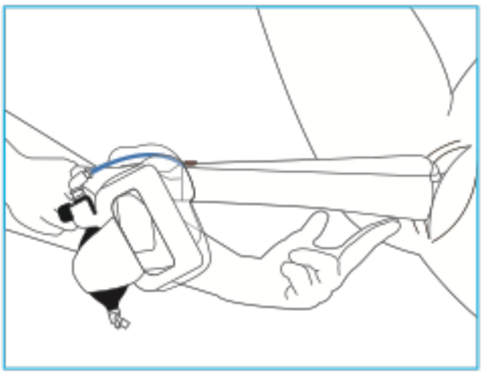


8.a. Fold the cup and gently insert it through the vulva and check it has regained its circular shape.

8.b. Check that there is no maternal tissue trapped between the cup and the fetal head.



9. With your hand on the handle of the applicator, gently push the device through the vulva. Use your other hand to guide the device and do not apply any force with it.



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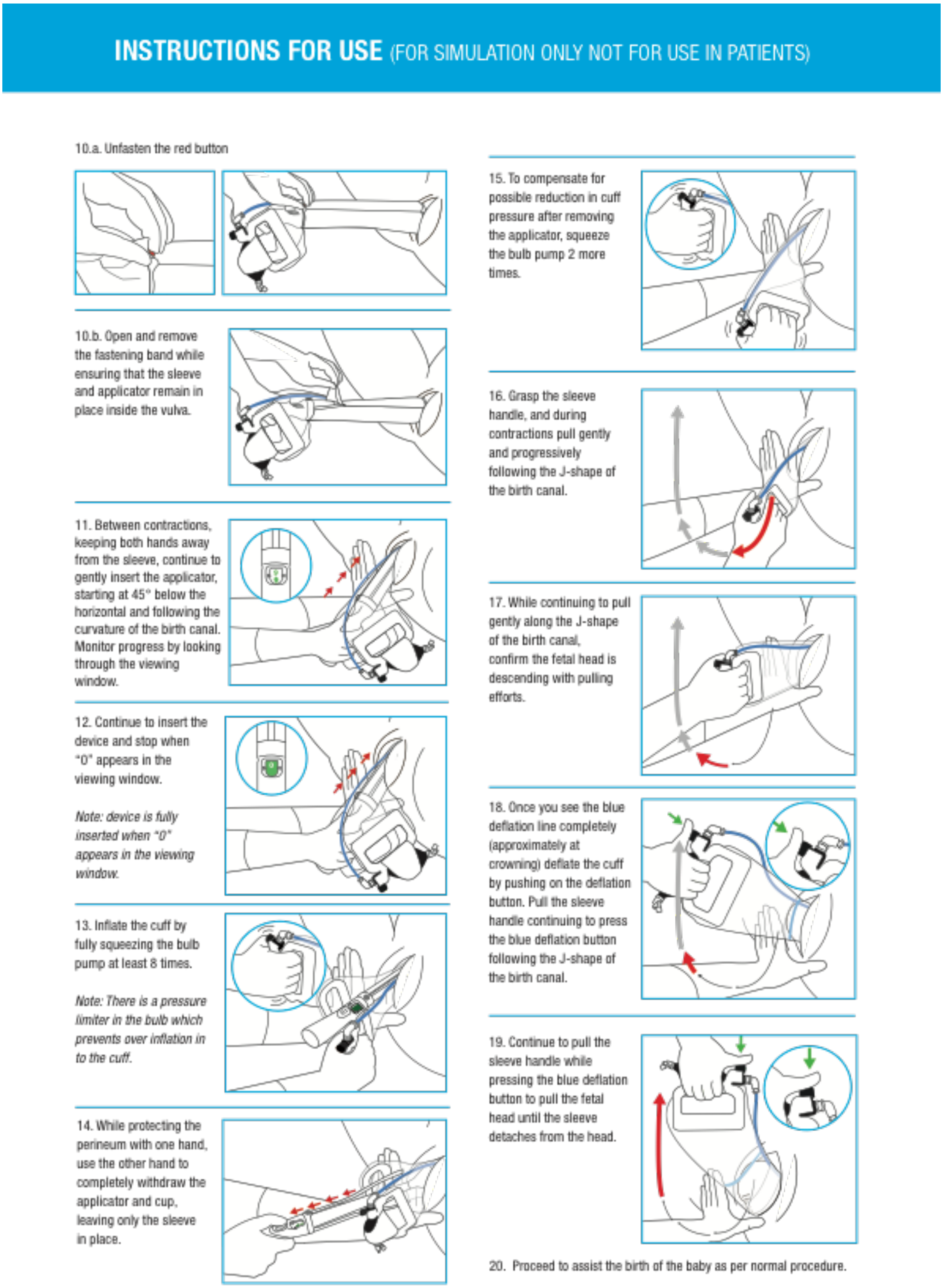


INSTRUCTIONS FOR USE (FOR SIMULATION ONLY NOT FOR USE IN PATIENTS)

10.a. Unfasten the red button

10.b. Open and remove the fastening band while ensuring that the sleeve and applicator remain in place inside the vulva.

11. Between contractions, keeping both hands away from the sleeve, continue to gently insert the applicator, starting at 45° below the horizontal and following the curvature of the birth canal. Monitor progress by looking through the viewing window.

12. Continue to insert the device and stop when "0" appears in the viewing window.

Note: device is fully inserted when "0" appears in the viewing window.

13. Inflate the cuff by fully squeezing the bulb pump at least 8 times.

Note: There is a pressure limiter in the bulb which prevents over inflation in to the cuff.

14. While protecting the perineum with one hand, use the other hand to completely withdraw the applicator and cup, leaving only the sleeve in place.

15. To compensate for possible reduction in cuff pressure after removing the applicator, squeeze the bulb pump 2 more times.

16. Grasp the sleeve handle, and during contractions pull gently and progressively following the J-shape of the birth canal.

17. While continuing to pull gently along the J-shape of the birth canal, confirm the fetal head is descending with pulling efforts.

18. Once you see the blue deflation line completely (approximately at crowning) deflate the cuff by pushing on the deflation button. Pull the sleeve handle continuing to press the blue deflation button following the J-shape of the birth canal.

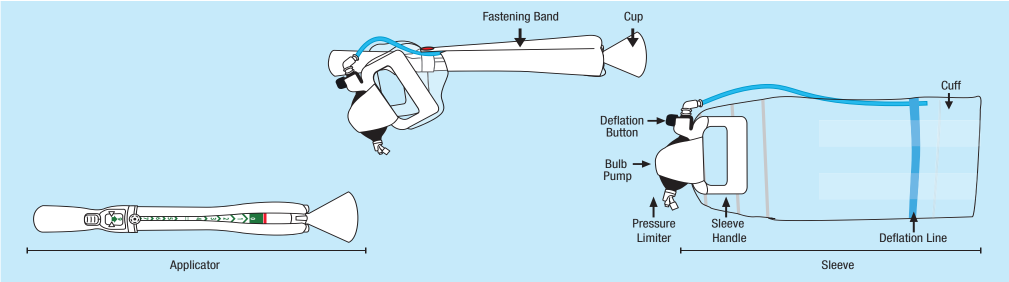
19. Continue to pull the sleeve handle while pressing the blue deflation button to pull the fetal head until the sleeve detaches from the head.

20. Proceed to assist the birth of the baby as per normal procedure.

B

Appendix 4 IFU v4

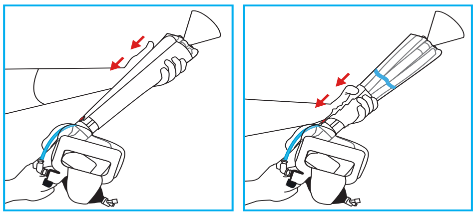
INSTRUCTIONS FOR USE (FOR SIMULATION ONLY NOT FOR USE IN PATIENTS)



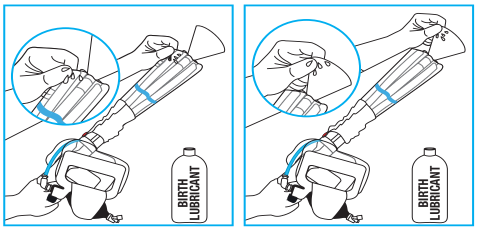
1. Ensure conditions for safe application of device are met:
   - a. Full dilation of cervix, fetal head +2 station or below, cephalic vertex presentation (OA, OP, OT positions), rupture of membrane
   - b. Provide adequate analgesia according to facility procedures
   - c. Position women in lithotomy position
   - d. Empty bladder
   - e. Re-confirm fetal position
   - f. Lubricate the birth canal

2. Remove BD Odon Device from packaging without compromising the sterility of the device.

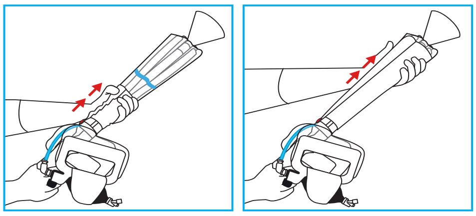
3. Pull back the fastening band until the blue deflation line is exposed.



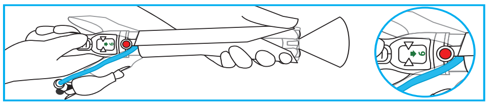
4. With the fastening band still intact, generously lubricate the inside and outside of the sleeve and the cup.



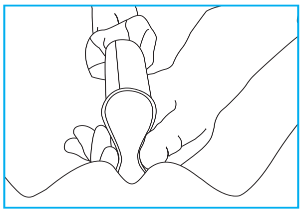
5. While holding the applicator handle gently slide the fastening band back to the top of the sleeve.



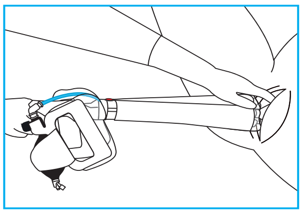
6. Grip the applicator handle and ensure the viewing window is facing upwards.



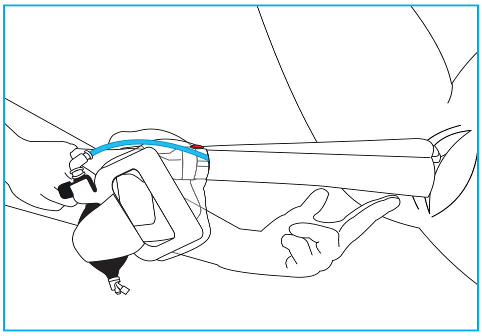
7. Fold the cup and gently insert it through the vulva and check it has regained its circular shape.



8. Check that there is no maternal tissue trapped between the cup and the fetal head.



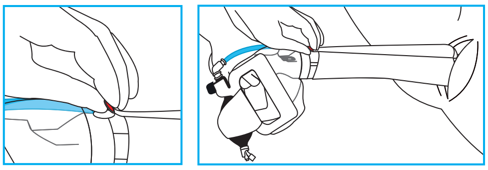
9. With your hand on the handle of the applicator, gently push the device through the vulva. Use your other hand to guide the device zand do not apply any force with it.



A

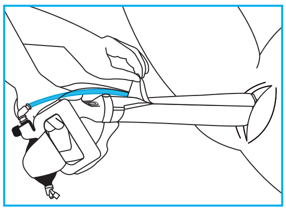
INSTRUCTIONS FOR USE (FOR SIMULATION ONLY NOT FOR USE IN PATIENTS)

10. Unfasten the red button

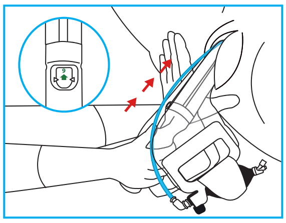


11. Open and completely remove the fastening band.

Note: ensure the sleeve and applicator remain in place inside the vulva.

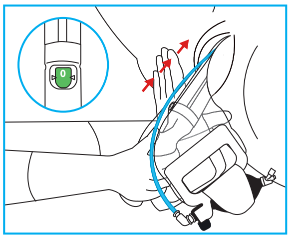


12. Between contractions, keeping both hands away from the sleeve, continue to gently push the applicator, starting at 45° below the horizontal and following the curvature of the birth canal. Monitor progress by looking through the viewing window.



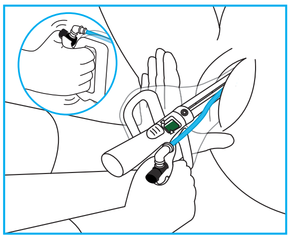
13. Continue to insert the device and stop when “0” appears in the viewing window.

Note: device is fully inserted when “0” appears in the viewing window.

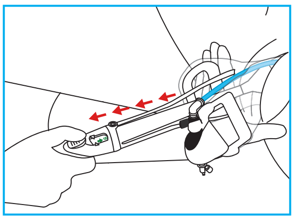


14. Squeeze the bulb pump fully and firmly at least 8 times to inflate the cuff.

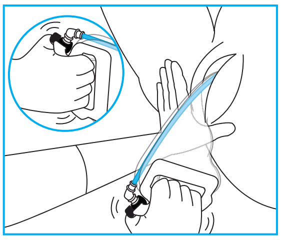
Note: There is a pressure limiter in the bulb which prevents over inflation in to the cuff.



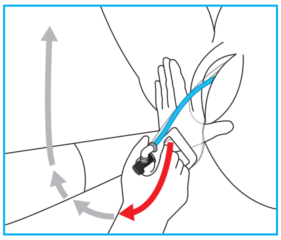
15. While protecting the perineum with one hand, use the other hand to completely withdraw the applicator and cup, leaving only the sleeve in place.



16. To compensate for possible reduction in cuff pressure, squeeze the bulb pump fully and firmly 2 more times prior to traction.

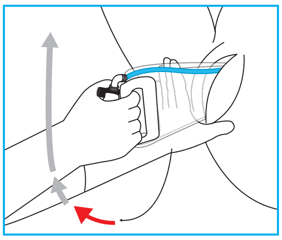


17. Grasp the sleeve handle, and during contractions pull gently and progressively following the J-shape of the birth canal.

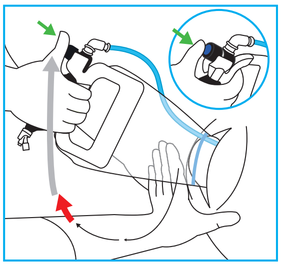


18. While continuing to pull gently along the J-shape of the birth canal, confirm the fetal head is descending with pulling efforts.

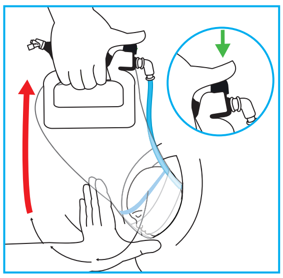
Note: if baby is not delivered at the first contraction repeat steps 16, 17 and 18 with any subsequent contractions.



19. Once you see the blue deflation line completely (approximately at crowning) deflate the cuff by pushing on the blue deflation button. Pull the sleeve handle continuing to press the deflation button following the J-shape of the birth canal.



20. Continue to pull the sleeve handle while pressing the blue deflation button to pull the fetal head until the sleeve detaches from the head.



21. Proceed to assist the birth of the baby as per normal procedure.

22. Discard disposable applicator and sleeve according to local appropriate procedure. Do not reuse.

B

Chapter 7 Discussion

7.1 The problem of complications in the second stage of labour

Complications in the second stage of labour make a significant contribution to maternal and neonatal morbidity and mortality worldwide - they are responsible for 4 to 13% of maternal deaths in Africa, Asia, Latin America and the Caribbean (5), and at least 0.4 deaths per 100,000 women worldwide (3).

OVB, in well-trained hands, remains the most effective tool to manage these complications (6). However, OVB is relatively under-used worldwide (26), and there are significant barriers to arresting the decline of OVB, let alone promoting its increased use. These downward pressures on the use of forceps and ventouse include poor public perception (16), a lack of provider awareness (50) and financial resources (27,53) and poor availability of training (53,90). Moreover, there are reasonable concerns about associated severe complications such as maternal anal sphincter injury, fetal skull fracture and subgaleal haemorrhage (11). Therefore, although they are to commended and supported, attempts to promote the use of current instruments (36,53,169) are unlikely to be sufficient in and of themselves – the development of a new device for OVB which has the potential to surmount some of these barriers is a reasonable and practicable strategy (8,50,170).

7.2 The proposed solution

The BD Odon Device is a new device for OVB. Since its first development by Jorge Odon, an Argentinian car mechanic in 2005, the BD Odon Device has been adopted, promoted and championed by the Chair of the WHO (170), a US Secretary of State (171), the United States Agency for International Development, the Government of Norway, the Bill & Melinda Gates Foundation, Grand Challenges Canada, the UK Government, the Korea International Cooperation Agency (172) and the world's largest medical device manufacturer (173). However, despite these hopes and expectations, there is a clear ethical (174) and legal (109,156) obligation to ensure that any new device is as; (i) safe, (ii) effective, and (iii) easy to use as possible prior to clinical use.

Given these demands, simulation may be the ideal medium in which to improve iteratively the design of any new device and its associated training materials.

7.3 Simulation as an evaluation and risk reduction methodology

Simulation has a proven track record in obstetrics for providing useful learning that can be leveraged by clinicians to improve outcomes. Simulation has provided raw quantitative data on the characteristics of specific obstetric manoeuvres (63,115) which can then be used to improve practice (88,116) and subsequently outcomes (110). In addition, simulation can provide a useful training space, and allows practitioners to learn and retain both knowledge (166) and skills (88) in an environment in which patients are not at risk of harm.

We therefore chose to develop and utilise a simulation methodology to identify systematically, quantify, and reduce where possible the risks associated with the use of the BD Odon Device.

Specifically, we sought to understand and mitigate the risks associated with the device's (i) location (ii) distention of the perineum (iii) traction force (iv) pressure and (v) pattern of use.

7.4 Summary of results

We found that:

(i) Location

The BD Odon Device sat in a repeatable location, between the fetal chin and nose anteriorly and at the level of C7 posteriorly, in all positions, stations, head sizes and inflation pressures, with the exception of OP and face presentation.

In OP positions, the device sat at or below the level of the fetal chin for approximately 1/3rd of simulations. As the device did not visibly compress the neck, there may be no contraindication to use the device in this situation. Further research is needed to establish the safety of neck placements.

The device could not be applied consistently and safely in face presentations.

(ii) Perineal distention

When used correctly (deflated prior to crowning), the BD Odon Device generated the same perineal distention, and is likely to be associated with similar risks to the perineum and anal sphincter, as Kiwi ventouse. When not deflated prior to crowning, the BD Odon Device generated greater perineal distention, and is likely to be associated with greater risks to the perineum and anal sphincter, than forceps. Therefore training in the appropriate use of the device is a critical component of its safe dissemination.

(iii) Traction

The BD Odon Device 'popped-off' at a lower traction force than forceps, but more than Kiwi ventouse. Therefore, the BD Odon Device may be able to deliver babies which cannot be delivered with Kiwi ventouse, but may not deliver those who require the level of traction that can only be provided by forceps. This may result in the BD Odon Device generating levels of traction-dependent adverse outcomes that are greater than Kiwi ventouse but lower than forceps.

(iv) Pressure

When correctly sited and using 80kPa inflation pressure on the cuff, the BD Odon Device generated a lower peak pressure on the fetal head than forceps.
When instruments were purposefully misplaced over the eyes, the BD Odon Device generated a lower peak pressure on the orbits than forceps. The BD Odon Device should therefore be associated with fewer pressure-related adverse events than forceps. When purposefully misplaced over the neck the BD Odon Device, compared to forceps, generated a greater peak pressure on the anterio-lateral aspect of the neck. While this pressure is sufficient to be able to theoretically occlude the carotid arteries, studies of complete carotid arterial occlusion in animals did not demonstrate a significantly reduced and sustained reduction in cerebral perfusion (152). Therefore it is unlikely that routine use of the BD Odon Device would result in clinically significant cerebral hypoxia to the fetus.

(v) Pattern of use

> Human Factors Engineering evaluations revealed multiple shortcomings with the original device design which impeded safe and effective use. These were mitigated through alterations to both the design of the device and the associated training materials. Following all alterations, all participants in a representative sample of users were able to correctly use the device to successfully complete a simulated OVB.

These findings suggest that the BD Odon Device has the potential to improve maternal and neonatal outcomes in the setting of complications in the second stage of labour, and should be evaluated in a clinical trial.

7.5 Strengths

This project was the first systematic attempt to identify, quantify and mitigate the risks associated with a new device in the field of obstetrics, and as a result the methodology was necessarily pragmatic. However, while the specific questions this study sought to address (location, perineal distention, traction, pressure and pattern of use) were original within this field, the chosen methodologies were not. Previous work using these techniques supports our contention that taken as a whole, the use of simulation provides a useful insight into how and why a device behaves the way it does, can suggest ways to improve its performance and validate any subsequent changes to design and training materials. Simulations were conducted using models, technologies and techniques which have been previously used in related fields and found to be useful. Specifically, the chosen maternal/fetal mannequin (the PROMPT Flex) has been previously evaluated and confirmed as having both construct and external validity (162). While the specific setting in which the mannequin was used in these experiments was different to those in which validity had previously been demonstrated, it is still reasonable to assume that the useful internal features of the mannequin (anatomically correct pelvic markers, accurate fetal head dimensions) will be preserved in the new setting and thus this choice of mannequin is justified. Moreover, these models (including those used to measure traction) have been widely utilised in the teaching of practical manoeuvres within obstetrics, and have shown improvements in clinical outcomes secondary to teaching interventions (92,110).

Furthermore, the use of pressure sensors, while new in obstetrics, is common within other medical specialities for the quantification and determination of distribution of pressure within biological processes (175).

The use of HFE has been found to be such a useful adjunct in the development of new medical tools, for both highly skilled practitioners (161) and unskilled care-users (160), that regulatory agencies within the USA (158), the UK (156) and the EU (109) have recently made it a compulsory part of new device development. In addition to this, the significant increases observed in the rate of successful use between the first and final versions of the BD Odon Device and its associated training materials makes a strong *prima facie* case for the utility of HFE in this context.

Lastly, this project benefitted from a close working relationship between clinicians and engineers. Within this relationship individuals felt able to share uncertainties and vocalise criticisms of both the device design and testing methodology. This free exchange of information and rapid cycles of risk identification, mitigation and validation enabled the project to comprehensively evaluate the behaviour of a new device in a relatively short space of time, limiting the delay in provision of this potentially useful technology to the mothers and babies who could benefit from it.

7.6 Limitations

As previously stated, the chosen methodology in this project was necessarily pragmatic. Within each study there are acknowledged limitations which may impact on the validity and generalisability of the findings.

Within all of the risk determination studies (location, perineal distention, traction and pressure), a single operator (SO'B) performed all simulations. While this reduces the risk of inter-operator errors, it also introduces the possibility of systematic error due to the specific, non-generalisable technique of this operator, which I acknowledge.

The chosen maternal/fetal mannequins, although accurately reflecting mean maternal and neonatal anatomy within the UK, may not accurately reflect the anatomy and therefore the behaviour of the BD Odon Device in populations with a higher rate of anthropoid-type pelvises.

Regarding the pressure studies, it is unlikely that the absolute pressures detected are accurate quantification of the pressure experienced by the fetus *in-vivo*, given our inability to mimic maternal tissues and contractions.

The HFE studies suffers from positive selection bias. We recruited participants from an acknowledged centre of excellence within the UK, and from international academic conferences within the specialty. Therefore, the participants may be more experienced, skilled or simply engaged than the average future user of the BD Odon Device, and may therefore demonstrate a shorter learning curve. While this is a strong possibility, it is unclear as to how this could be overcome. Participation in any research study must be voluntary, and so it will always be challenging to engage those who, through lower levels of enthusiasm and engagement, do not wish to do so. This is a systematic problem across all HFE studies and no consensus has yet emerged as to how this can be reduced. While the true learning-curve can and should be studied in both the clinical trial (174) and post-market surveillance (109) of any new device, the question of how to estimate this from results generated by a group of engaged early-adopters in simulation-based HFE studies remains unanswered.

7.7 Generalisability of findings and methodology

Given the lack of any clinical validation of these simulation methodologies, it is unknown how generalisable the results of the location, perineal distention, traction and pressure studies are. Should clinical testing confirm that the BD Odon Device does indeed sit between the fetal nose and chin anteriorly and C7 posteriorly, and generates similar levels of perineal tearing as Kiwi ventouse when correctly deflated prior to crowning, the simulation findings should be considered to be validated and generalisable to the population of women and babies with similar anatomy to the mannequins used in the study.

Regarding the pressure study findings, while it is likely that the reported pressure values are not quantitatively accurate to those experienced by the fetus, it is likely that the results are internally consistent. The pressure experienced by a fetus undergoing a BD Odon Device birth, whatever it may be, is likely to be less than forceps and greater than Kiwi ventouse.

HFE as a methodology is already widely implemented in other settings and fields, and this project adds weight to the contention that it has a useful role to play within obstetrics too.

7.8 Recommendations for further work

This thesis has demonstrated a new methodology for evaluating and reducing the risks of a new device for OVB. The next step to validate this methodology is a clinical trial of the device studied to determine if my findings (such as a lower rate of successful birth and neonatal trauma than forceps and widespread ease of use by practitioners) are reflected in clinical practice. While these findings could be evaluated through comparisons of clinical outcomes between single-device non-comparative studies (case series), internal validity can only be established through a comparative study of the BD Odon Device versus either Kiwi ventouse or forceps. Given the worldwide pattern of use of instruments and similarities of device and indication (single use, any position, able to generate flexion and rotation), a clinical trial versus Kiwi ventouse may be the most practical and useful comparison.
Such a clinical trial is currently in development in Bristol, UK and Besancon, France, with funding provided by the Bill & Melinda Gates Foundation.
The results of this complex trial will either confirm or reject the hypotheses of this thesis that it is possible to use simulation technology to prospectively quantify the likely characteristics of a new instrument for operative vaginal birth.

7.9 Conclusion

The findings of this thesis suggest that the BD Odon Device has the potential to improve maternal and neonatal outcomes in the setting of complications in the second stage of labour and should be evaluated in a clinical trial.
Moreover, the findings and alterations made to the device design, instructions and training materials clearly demonstrate the utility of simulation evaluation of new devices for OVB as being a useful and practical way of reducing the burden of risks on women and their babies prior to clinical evaluation.

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